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RELEASING GENETICALLY ENGINEERED ORGANISMS INTO THE ENVIRONMENT

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HEARING

BEFORE THE

SUBCOMMITTEE ON
TOXIC SUBSTANCES AND ENVIRONMENTAL
OVERSIGHT

OF THE

COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

NINETY-NINTH CONGRESS

SECOND SESSION

MAY 16, 1986

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CONTENTS

OPENING STATEMENTS

	Page
Baucus, Hon. Max, U.S. Senator from the State of Montana	2
Burdick, Hon. Quentin N., U.S. Senator from the State of North Dakota	9
Durenberger, Hon. Dave, U.S. Senator from the State of Minnesota	1

WITNESSES

Bentley, Orville G., Assistant Secretary for Science and Education, Department of Agriculture	29
Written statement	80
Responses to additional questions	89
Goldhammer, Dr. Alan, director, technical affairs, Industrial Biotechnology Association	39
Responses to additional questions	105
Mellon, Margaret, director, Toxics Program, Environmental Law Institute	38
Written statement	97
Responses to additional questions	103
Moore, John A., Assistant Administrator for Pesticides and Toxic Substances, Environmental Protection Agency	12
Written statement	65
Responses to additional questions	76

ADDITIONAL MATERIAL

Statements:	
Volkmer, Hon. Harold, a Representative in Congress from the State of Missouri	46
General Accounting Office	48

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RELEASING GENETICALLY ENGINEERED ORGANISMS INTO THE ENVIRONMENT

FRIDAY, MAY 16, 1986

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON TOXIC SUBSTANCES AND
ENVIRONMENTAL OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:15 a.m., in room SD-406, Dirksen Senate Office Building, Hon. Dave Durenberger (chairman of the subcommittee) presiding.

Present: Senators Durenberger, Baucus, and Burdick.

OPENING STATEMENT OF HON. DAVE DURENBERGER, U.S. SENATOR FROM THE STATE OF MINNESOTA

Senator DURENBERGER. The hearing will come to order.

Good morning, I apologize to everyone in this room for my late arrival.

The subject of our hearing this morning is biotechnology or intentional release of genetically engineered organisms into the environment for experimental and commercial purposes.

The subcommittee has been monitoring developments in the field of biotechnology for more than 2 years now and late last year Senator Baucus and I joined together as sponsors of a bill which would provide EPA with new authority to regulate the use and the distribution of biotechnology.

But that legislation is not the focus of our hearing this morning. We will not be proposing new authorities. Rather, we will be examining the existing authority of EPA and USDA to determine whether that authority is sufficient to protect public health and the environment from the hazards proposed by this new technology.

Recent events are not reassuring. In November 1985, EPA approved the experimental test of an organism engineered to prevent the formation of frost on strawberry plants. This permit came after considerable public debate and court tests. The record on the organism and the proposed use was well developed. Nevertheless, the project has encountered extraordinary difficulties. It was only after it had granted the permit that EPA discovered that the company had made unauthorized releases of the organism and had not properly conducted some of the preliminary tests and had not fully disclosed the nature of the proposed experimental release to the Environmental Protection Agency.

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EPA, therefore, was forced to withdraw the permit and has now fined the company the maximum amount allowed under the law, $20,000.

Following immediately on this muddle at EPA, we learned that USDA, U.S. Department of Agriculture, had approved a field test of a genetically-engineered vaccine in violation of National Environmental Law and in violation of its own biotechnology review policy.

Again, a Federal agency was forced to withdraw a permit it had already issued. USDA conducted a 20-day internal review that was sufficient to clear its own conscience. But it appears that two Texas universities and the National Institutes of Health will not be so easily persuaded.

This subcommittee has followed these events closely. In both cases it appears that the organisms that have been engineered are of low risk. Both were developed by deleting genetic material from an organism and did not involve the transfer of genetic material from one organism to another. The altered bug was proposed to be returned to an environment from which its parent was originally isolated. So, the risk of experimental releases in these two cases appears to have been low.

But the process to review and regulate these experiments failed completely. Two different Federal agencies using two different authorities and taking two different approaches have produced exactly the same result, and it is not a happy result.

The failure of the processes in these cases is of great concern to this subcommittee. But even more troubling is the prospect that among the next few proposals for intentional release there will be organisms which have been engineered in ways that present significant risk to the environment.

We will be discussing one such proposal today, and we will want to know why the process which failed in the case of ice minus and the process that failed in the case of the swine vaccine should now be relied upon to protect human health and the environment from organisms that are engineered to be killers.

Max, do you have an opening statement?

Senator BAUCUS. Mr. Chairman, I have a prepared statement I would like to include in the record.

Senator DURENBERGER. Without objection, your statement will be part of the record.

OPENING STATEMENT OF HON. MAX BAUCUS, U.S. SENATOR FROM THE STATE OF MONTANA

Senator BAUCUS. Mr. Chairman, I think this hearing, one of many hearings that this Congress has on this subject, biotechnology is potentially the most important new technology I think for the rest of this decade. There are obvious tremendous potential benefits; there are also obvious tremendous potential risks, as with any important new technology.

It is important, therefore, that Congress and particularly the various agencies responsible for this technology and the regulation of this technology to move forward much more forthrightly, much

more aggressively, much more thoroughly than they have in the past.

There is a duplication among agencies, but even so, within each agency there is a dereliction of agency responsibility to develop technology.

This country is also facing competitive challenges from overseas. Japan, for example, is moving much more aggressively in developing biotechnology. If the United States is to meet competitive challenge and also to develop the technologies to help American agriculture, to help American environment, among many new applications of biotechnology, agencies have to move much more thoroughly and forthrightly in their development.

We also face the problem of insurance. Because it is new, because of the technology's tremendous potential benefits and potential risks, the insurance companies have not yet developed the requisite insurance to provide more confidence to the American public to the companies involved to proceed.

These are all subjects that will be the subject of this hearing and many other hearings, and I strongly advise agencies to move ahead more quickly so that the American public can be afforded the benefit of these technologies and that the potential risks of these biotechnologies be significantly reduced or at least better understood. It is critical. And I just urge us to proceed as quickly as we possibly can.

[Senator Baucus' written statement follows:]

STATEMENT OF THE
HONORABLE MAX BAUCUS
SUBCOMMITTEE ON TOXIC SUBSTANCES
AND ENVIRONMENTAL OVERSIGHT

MAY 16, 1986

MR. CHAIRMAN, THANK YOU FOR SCHEDULING THIS IMPORTANT OVERSIGHT HEARING ON THE RELEASE OF GENETICALLY ALTERED ORGANISMS, OR BIOTECHNOLOGY.

SPECIFICALLY, WE WILL EXAMINE THE PROCESS USED TO ASSURE THE AMERICAN PUBLIC THAT THIS TECHNOLOGY WILL IMPROVE THE QUALITY OF LIFE, NOT DEGRADE THE ENVIRONMENT. THIS TECHNOLOGY IS A NEW TECHNOLOGY THAT HAS TREMENDOUS POTENTIAL, WHETHER THROUGH IMPROVED AGRICULTURE, NEW DRUG THERAPY OR USES WE CAN'T YET CONCEIVE. BUT JUST AS THERE IS POTENTIAL TO MOVE AHEAD, THERE IS POTENTIAL THAT THIS TECHNOLOGY COULD UNLEASH UNCONTROLLED AND UNINTENDED ENVIRONMENTAL DAMAGE.

THE DEPARTMENT OF AGRICULTURE'S DECISION TO GRANT THE WORLD'S FIRST LICENSE TO MARKET A LIVING, GENETICALLY ALTERED VIRUS, AND THE ENVIRONMENTAL PROTECTION AGENCY'S DECISION TO APPROVE THE FIRST DELIBERATE RELEASE OF A BIOENGINEERED PESTICIDE INTO THE ENVIRONMENT WERE CRITICAL DECISIONS. WE NEED TO CLOSELY EXAMINE HOW THESE DECISIONS WERE REACHED.

THE DIVERSITY OF USES FOR BIOTECHNOLOGICAL TECHNIQUES SPANS A BROAD SPECTRUM OF THE UNITED STATES ECONOMY. AMERICAN COMPANIES ARE BEGINNING TO SPEND MILLIONS OF DOLLARS TO DEVELOP PRODUCTS WITH MEDICAL, AGRICULTURAL, ENVIRONMENTAL, AND INDUSTRIAL USES.

BUT WITHOUT THE SUPPORT AND CONFIDENCE OF THE AMERICAN PUBLIC, THE BIOTECHNOLOGY REVOLUTION WILL WITHER ON THE VINE.

GENETIC ENGINEERING, LIKE MANY OTHER NEW TECHNOLOGIES, PRESENTS SOCIAL, ENVIRONMENTAL AND ECONOMIC UNCERTAINTIES. AN UNDERLYING PROBLEM

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WITH USDA'S AND EPA'S APPROVAL PROCESS FOR ENVIRONMENTAL RELEASES STEMS FROM THE UNCERTAINTY CREATED BY UNCLEAR AND CONTRADICTORY REGULATIONS.

AS MORE COMPANIES PREPARE TO MOVE RESEARCH FROM THE LABORATORY INTO THE OPEN ENVIRONMENT, IT IS CLEAR THERE IS A NEED FOR AGENCIES TO PLAY A MORE ACTIVE ROLE IN REGULATING THE INDUSTRY TO ENSURE THAT THE PUBLIC'S WELFARE IS PROTECTED. THE PUBLIC WANTS TO KNOW; THEY HAVE A RIGHT TO KNOW; AND THE FEDERAL GOVERNMENT HAS A RESPONSIBILITY TO LET THEM KNOW.

NO ONE DISPUTES THAT THERE IS CONTROVERSY SURROUNDING EPA'S AND USDA'S APPROVAL OF GENE-ALTERED MICRO-ORGANISMS AND THEIR RELEASE. BOTH AGENCIES HAVE HAD LAWSUITS FILED AGAINST THEM. WE CAN EXPECT THESE TYPES OF LAWSUITS. IT IS A NEW AREA, A NEW TECHNOLOGY, AND THERE ARE NEW CONCERNS. BUT, BEYOND THIS NORMAL CONCERN, THERE ARE FUNDAMENTAL QUESTIONS ABOUT THE PROCESS THAT NEED TO BE ADDRESSED.

THE BIOTECH INDUSTRY IS ALSO CONCERNED ABOUT THE REGULATORY PROCESS. THEY NEED CERTAINTY. USDA'S HANDLING OF RELEASES HAS ALREADY LED TO THE

CALGENE COMPANY TO TEMPORARILY SUSPEND ITS APPLICATION TO FIELD TEST AN ENGINEERED TOBACCO PLANT. THEY WANT TO MOVE FORWARD WITH THEIR EXPERIMENT, BUT UNDER THE CURRENT SITUATION AT AGRICULTURE, IT APPEARS THAT THEIR FIELD TEST WILL END UP IN COURT INSTEAD OF IN THE FIELD. CALGENE IS NOT ALONE. MANY OTHER BIOTECH COMPANIES' GLOBAL MARKETING PLANS ARE CLOUDED BY THE UNCERTAINTIES OF HOW DIFFERENT AGENCIES WILL REGULATE THE NEWLY EMERGING PRODUCTS OF BIOTECHNOLOGY.

THERE IS A NEED TO SET PRUDENT STANDARDS FOR BIOTECHNOLOGY RESEARCH AND TESTING. THE OVERALL AIM OF THESE EFFORTS MUST BE TO RESTORE PUBLIC CONFIDENCE SO THAT THE SAFE DEVELOPMENT OF THE BIOTECHNOLOGY INDUSTRY IS ENSURED.

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Senator DURENBERGER. Senator Burdick.

Senator BURDICK. Mr. Chairman, in the interest of time in hearing the witnesses, I will put it in the record.

[Senator Burdick's statement follows:]

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STATEMENT BY QUENTIN N. BURDICK
REGULATION OF BIOTECHNOLOGY HEARING
SENATE ENVIRONMENT AND PUBLICK WORKS
MAY 16, 1986

BIOTECHNOLOGY HAS OPENED A NEW AND EXCITING DOOR FOR AGRIBUSINESS. ALREADY ON THE HORIZON WE SEE THE DEVELOPMENT OF NEW STRAINS OF PEST RESISTANT CROPS, NEW METHODS OF FROST PROTECTION, AND THE POSSIBLE REPLACEMENT OF OBSOLETE AND DANGEROUS PESTICIDES WITH SAFER, MORE EFFECTIVE METHODS.

CURRENT FEDERAL REGULATION OF BIOTECHNOLOGY CENTERS ON A VOLUNTARY APPROACH BASED ON GUIDELINES WHICH WERE ORIGINALLY AIMED AT PREVENTING AN ACCIDENTAL RELEASE, HOWEVER, RESEARCH ADVANCEMENTS HAVE OUTSTRIPPED THESE GUIDELINES. SOME COMPANIES NOW WANT TO DELIBERATELY RELEASE ALTERED MICRO-ORGANISMS IN FIELD TESTS TO GATHER MORE INFORMATION BEFORE THEY START COMMERCIAL PRODUCTION.

THE MOST PRESSING BIOTECHNOLOGY ISSUE CURRENTLY FACING CONGRESS IS JUST HOW TO REGULATE THE DELIBERATE RELEASE OF GENETICALLY ENGINEERED ORGANISMS. THE REGULATORY SCHEME MUST BE CONSISTENT TO ALLOW AN ORDERLY PROGRESSION FROM RESEARCH, TO LICENSING AND APPLICATION.

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THE HISTORY OF THE FEDERAL GOVERNMENT'S HANDLING OF THE RELEASE ISSUE HAS BEEN INCONSISTENT AND CONFUSING. INCOMPLETE AND MISLEADING DATA HAVE BEEN USED TO MAKE REGULATORY DECISIONS, AND EVEN WITHIN THE SAME AGENCY, VIRTUALLY IDENTICAL PRODUCTS HAVE BEEN TREATED TO WHOLLY DIFFERENT REGULATORY REQUIREMENTS. A MORE CONSISTENT REGULATORY FRAMEWORK IS NECESSARY SO THAT ALL RELEASES OF GENETICALLY ENGINEERED ORGANISMS ARE SCRUTINIZED BEFORE THEY OCCUR. COMPANIES DEVELOPING PRODUCTS FOR RELEASE WILL BE FREED FROM THE CURRENT ATMOSPHERE OF UNCERTAINTY BY A CLEAR SET OF GROUND RULES.

PART OF THE PROBLEM MAYBE THE FEDERAL GOVERNMENT'S PRACTICE OF DIVIDING UP THE TASK OF REVIEWING RELEASES BETWEEN VARIOUS FEDERAL AGENCIES, SUCH AS THE ENVIRONMENTAL PROTECTION AGENCY, U.S. DEPARTMENT OF AGRICULTURE, AND THE NATIONAL INSTITUTE OF HEALTH. SOME OF THESE AGENCIES, PARTICULARLY THE DEPARTMENT OF AGRICULTURE, HAVE HAD INTERNAL DIFFICULTIES IN REVISING THEIR REGULATORY PROCEDURES TO COPE WITH THE RISK ASSESSMENTS NEEDED BEFORE PERMITTING A RELEASE. BY INSURING THAT ALL RELEASES ARE REVIEWED BY A SINGLE BODY, AND BY ESTABLISHING CLEAR, COMPREHENSIVE DEFINITIONS, WE SHOULD BE ABLE TO MOVE BEYOND THE CURRENT CONTROVERSIES CREATED BY INCONSISTENT FEDERAL MANAGEMENT.

CONGRESS MUST ALSO RECOGNIZE THE FACT THAT THERE IS A LIMITED AMOUNT OF INFORMATION AVAILABLE TO EVALUATE THE SAFETY OF MANY KINDS OF RELEASES. AN INFORMATION VOID HAS DEVELOPED BECAUSE WE ARE SPENDING ONE BILLION DOLLARS PER YEAR ON BIOTECHNOLOGY RESEARCH AND ONLY $40 MILLION ON ECOLOGY. THE GOVERNMENT SHOULD NOT BE RUBBERSTAMPING ANY REQUEST UNTIL IT KNOWS FOR SURE WHETHER IT WILL HARM THE PUBLIC OR ENVIRONMENT, INFORMATION WHICH ONLY THE LONG NEGLECTED SCIENCE OF ECOLOGY CAN PROVIDE.

SINCE MOST OF THE APPLICATIONS FOR DELIBERATE RELEASES ARE FOR NEW AGRICULTURAL PRODUCTS, I AM CONCERNED ABOUT FARMERS. THEY ARE MOST AT RISK FROM ACTUAL PRODUCT EXPOSURE AND UNFORSEEN DAMAGE TO CROPS OR LIVESTOCK COULD THREATEN THEIR LIVELIHOOD. ON THE OTHER HAND IF THESE REGULATORY PROBLEMS ARE NOT WORKED OUT COMPANIES MAY ABANDON AGRICULTURAL RESEARCH AND PREVENT FARMERS FROM GAINING ACCESS TO PRODUCTS OF GREAT POTENTIAL BENEFIT.

THE UNITED STATES IS PRESENTLY THE WORLD'S LEADER IN BIOTECHNOLOGY RESEARCH. IF WE CAN PROVIDE THE NECESSARY SAFEGUARDS FOR THE PUBLIC AND THE ENVIRONMENT, THROUGH CONSISTENT REGULATION, THERE IS NO REASON WHY WE CANNOT MAINTAIN OUR POSITION IN FIRST PLACE.

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Senator DURENBERGER. Let me indicate that unless there is an objection, I will introduce in the record the prepared testimony of the Honorable Harold Volkmer of Missouri which would have been presented today had he been able to be here and the testimony of Brian B. Crowley of the General Accounting Office on the Review of the Department of Agriculture's Biotechnology Research Efforts and Regulatory Programs and Activities which would have been presented today.

And not hearing an objection, both of those statements will be made part of the record of this hearing. (See pp. 46 and 58.)

What I intend to do is ask Dr. John Moore to testify first. Then to take our two representatives of the Department of Agriculture, Mr. Bentley and Mr. Tracy, second. Then after we have completed those two sets of witnesses, to ask Margaret Mellon and Dr. Alan Goldhammer to come up as a panel of two.

So we will begin with Dr. John Moore, the Assistant Administrator for Pesticides and Toxic Substances of the Environmental Protection Agency and welcome you back again, Jack, the second day in a row.

It is amazing, now that tax reform is half over we get to see more of you.

Your full statement will be made part of the record and you may proceed to summarize it in your usual succinct fashion.

STATEMENT OF JOHN A. MOORE, ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES, ENVIROMENTAL PROTECTION AGENCY

Dr. MOORE. Thank you, Senator. I will summarize my prepared statement and paraphrase it, if you will.

As I believe the committee well knows, the development of registration of pesticides is under the jurisdiction of the Federal Insecticide, Fungicide, and Rodenticide act, and section 5 of that act allows EPA to grant an experimental use permit for the limited use of an unregistered pesticide. Regulations that were promulgated in 1975 basically require this EUP for all tests on greater than 10 acres that involve greater than 1 surface acre of water.

In the fall of 1974, we issued an interim policy on small-scale field testing of certain microbial pesticides. Our purpose in doing that was to implement a mechanism for evaluating and addressing the potential risks raised by small-scale use of genetically engineered or nonindigenous microbial pesticides.

For example, we wanted an opportunity to evaluate these bacteria's potential to survive in the environment, to replicate in the environment, to transfer genetic material, to spread within that environment, and also to have some sense as to whether or not there may be natural control mechanisms that may keep them from unlimited reproduction in growth.

I would like to emphasize that our particular interest in nonindigenous microbes or engineered microbes are primarily directed toward the environmental release aspects of these, not studies in a controlled laboratory or growth chamber or similar circumstances.

This interim policy which is still in effect requires that we be notified 90 days before one proposes to conduct one of these experi-

ments. We ask that a certain type of information be provided to us along with that notification and on the basis of our review of that data we make a determination of whether or not a formal experimental use permit will or will not be required. If a formal experimental use permit is required, we at that time usually articulate what additional data if any we would like to have accompany such a permit.

Once that material is provided, we then review that material within the pesticide program and as well as within the Agency, and form a draft opinion as to the completeness, adequacy of the data and any concerns that we may have.

Simultaneously with that, we have elected to avail ourselves of the opportunity of asking our sister agencies to review the application as well. We also have set up an ad hoc subcommittee for each and every one of these organisms chaired by a member of the Scientic Advisory Panel. The reason for the ad hoc nature is that the diversity of the requests are such that the mix and blend of the scientific talent and experience that one would want would vary dependent upon the nature of the request.

Ice minus certainly would dictate that we would want certain types of scientific expertise that may well be different from a proposed experimental use permit that is going to deal with microbes intended to grow in the root of a corn plant.

We have also published a notice in the Federal Register indicating that we have received and are considering such a request. The notice affords an opportunity for public comment. We have submitted our tentative findings within the Agency as well as the full data sent to the panel. The panel of the ad hoc committee meets openly, discusses their views as well as the views provided by others, and renders an opinion to the Agency. The Agency then, on the basis of public comments that have been received, the SAP's expert opinion, the opinion of the Pesticide Program, others in the Agency, as well as other agencies, decides whether or not to grant such an experimental use permit and if so, under what conditions.

To date we have basically utilized this process in three instances, one being the AGS request. Subsequent to that was the request of Dr. Lindow, et al., from the University of California and then a request that is still pending from Monsanto Chemical Co.

We have, as you alluded to in your opening statement, granted two experimental use permits. One to the AGS and more recently this week announced the granting of an experimental use permit to Dr. Lindow, University of California, to again conduct experiments involving ice minus bacteria, in this case not on strawberry plants, but on potato plants in an area in northern California.

After granting the AGS permit, we have instituted two other permit reviews. One, we are taking a much closer scrutiny of the site that is being proposed for the experimental use permit. We did, for example, visit the site in California prior to our granting a decision and have also visited the proposed site that Monsanto would hope to use or at least stated they were planning to use in their experiments in Missouri should we grant that proposal.

Senator DURENBERGER. Is that so you can talk to people? That's not a facilities inspection, is it?

Dr. MOORE. We visited the actual sites; yes.

Senator DURENBERGER. But I mean the purpose was to talk to the people involved more so than——

Dr. MOORE. Talk to the people involved and also to get a sense of what is there on the site. Where is it in proximity to other land, if indeed one had to impose some type of control mechanism which, for example, was built into these experimental use permits. If you get bacteria beyond the test site above a certain quantity, there are provisions in there whereby you will spray with a microbicide to try to control the organism and things of that sort. We want to see where the site is in relation to somebody else's property.

We also are interested in, for example, where it is in relation to other housing and where it is in relation to drainage and things of that sort.

As a direct result of the AGS circumstances that came to light after we had awarded the permit, we have also gone to the University of California and have also visited Monsanto to look at the records and I would call it a record check an a record inspection as opposed to a detailed audit. The purpose of the inspection was to see if they are in possession of records that do indeed underpin the data that they have submitted to the Agency in support of their experimental use permit.

While the process for the two ice-minus proposals are complete in that we have granted a permit, as you point out, subsequent to granting the AGS permit, we have pulled that back and held it in abeyance pending resubmission of certain data sets as well as identification of a new site that they are looking for to consider doing those experiments.

But I would also just conclude, Senator, by saying that I would not characterize the AGS experience as one of failure. I think that connotes the wrong message to the public. I think the process was a success. I think the process is working. It's an open process. It's a detailed process. The process demonstrates the benefit of availing ourselves of the best scientific opinion as to the risks that are associated with those experiments.

As you pointed out in your statement, the collective wisdom is that the risks that are involved in these experiments are held to be minimal not just by the Agency, but also by all of the expert opinion. Indeed, if there was a problem that was associated with the AGS permit it was at least identified in our levying of administrative penalties in that instance and that the data that was submitted to us was somewhat misleading. And once that was brought to our attention, I believe it was within a period of 3 weeks that we had investigated that allegation, had completed our investigation, drawn a conclusion, and levied a fine. And I think that if there was an error in that process mechanically, it would be that one can identify through policies, through regulations, et cetera, exactly what you want to be done, and if somebody subverts that wittingly or unwittingly, it is impossible for EPA or any other regulatory agency to in each and every instance review each and every piece of data that's going to be submitted prior to our taking action. I think that's just a fact of life.

In retrospect, we would have liked to have visited the site with AGS prior to our granting the permit, not because there's a risk involved in the experiment, but again, as was pointed out in the

opening comments of the committee members, the public is greatly interested and also maybe to some degree concerned about both the benefits and the possible adverse effects of biotechnology. And to the degree that we can develop a process including the inspection of the site in rendering expert opinion on the adequacy of that site as well, I think the public will be better served, particularly in the local areas where the experiments are going to be conducted, that indeed those aspects were also reviewed and also have available to them the benefit of sound advice.

That concludes my statement, Senator.

Senator DURENBERGER. Let me pick up where you left off. You at least have left me with the impression that there's "sort of nothing to worry about." What we are headed into here is a mutual set of experimentations. While the experimentations are going on in the biotechnology field, the Government is also going to experiment with its relationship with the industry.

At the end of your statement, I think you pointed to the problem with that which is the absence of public concern for the effects of biotechnology, and as long as we are just taking one bug out and sending it back where it came from, maybe there isn't a lot to worry about.

But the realities of why we have watched this for 2½ years and held some hearings in this subcommittee is not to scare the public; it is to prepare people like you and institutions like this Government and the biotechnology industry for the realities that come with the unknown.

I often feel like I am too close to the problem to worry about it. I sit as chairman of the Intelligence Committee and watch what other people cannot see of the development of the Chernobyl disaster, and I ask myself, why in the world is every single constituent of mine uptight today about what happened in Chernobyl, and they were.

My colleagues were coming to those of us on the Intelligence Committee and saying, do you know something that we don't know that will reassure us? The world went into a temporary panic and a long-term concern. In Europe, milk got dumped all over and people in Poland and Sweden worried about the quality of their crops.

My calls went from, "I'm going to Europe or the Far East, am I safe from terrorism?" to "Am I safe from the dangers of radiation?"

The point is that the concern for the unknown and for experimentation in the unknown and the conversion of the unknown to the known and the beneficial, as Max so well pointed out in his statement, is an experimental process in and of itself.

I would like you to explain in a little more detail why I have to be satisfied with a statement from the Environmental Protection Agency that says "we can't examine each and every piece of data. Even though the data was misleading, we have to accept that that was misleading and we'll give them a $20,000 fine and we do something else." And that we ought to proceed through, in effect, a period of experimentation and we ought to gradually develop policies and regulations and so forth.

Tell me a little bit about the nature of the industry or the nature of Government regulation or the interface between the two in this situation that would make the case that I think you are trying to make which is "don't overly concern the American public, we are just doing our job. This was not a failure. You can expect to have some of these cases reported on the front pages of our newspapers and on our television. Don't worry about it."

Dr. MOORE. Senator, let me start off by saying I do feel that I and the Agency do have a burden to indeed establish a credible process in the eyes of the public, particularly as it relates to biotechnology. Because failure to do that will nip the industry in the bud. And I do not think anybody wants that.

The point I was trying to make is that we can't reveiew each and every piece of information. It is an issue of practicality. In the Pesticide Program alone, we have 40,000 pesticide registrations. Each registration is accompanied or buttressed by hundreds if not thousands, maybe tens of thousands, of pages of documentation. It is literally impossible for us to go out and verify every number on every page or every statement on every page. We would never get to the analysis of the data, let alone reaching a decision.

Something has been learned from the AGS process. At least for the near foreseeable future as it deals with products of biotechnology, since we are trying to establish a track record that the public will have confidence in, that indeed we will take special scrutiny in this area. In some instances the number of the people that we will be dealing with are not used to the process that is involved or required by regulatory agencies. This includes AGS as well as new companies that don't have a track record of dealing with this regulatory agency or any other regulatory agency.

In the Lindow experiment, Dr. Lindow, an academician from the University of California at Berkeley, had nothing in his background that necessarily gave him a track record of experience as to what we want and how we want it. He probably was not aware that if it is specified in policy or regulations, that there may not be a whole lot of flexibility in the form of style in which that data——

Senator DURENBERGER. What does that mean? Ignorance and naiveté are a license unto themselves?

Dr. MOORE. Possibly both. Possibly both.

Senator DURENBERGER. A license to do what?

Dr. MOORE. No, no. There might be some naiveté associated, unfamiliarity with the process. I think we should not lose sight of the fact that in the intensive audit that we did do on the AGS data book, for example, the only data that was found to be in question was that one experiment that was conducted on a rooftop. All the other data was sound and solid.

Obviously, with the benefit of hindsight I can characterize, I think, their decision to conduct that experiment as obviously one that was flawed. It is probably easy for me to say, but nonetheless, they did do it. And interestingly enough, they did it to gather data in order to get the legal EUP.

The data that was presented to us in this case was presented to us in a way that we would have no reason to believe—in fact, we would have been led to believe that it was done probably in a greenhouse-type of environment. And it was only brought to our at-

tention that it had not been done this way, and then upon inspection of the actual data records that were in possession of the company that it became apparent that it indeed had been done on a rooftop.

Now, I do not think I can catch all of them.

Senator DURENBERGER.These are the relatively easy cases I take it, because we have agreed that this is just sending the organism back to its native environment.

I assume, having had you say all of that, we have some tougher judgments coming up and I understand just around the corner we have proposals to release organisms that are engineered in effect to be killers, as I said in my opening statement.

How should we and the American public view these, what you have characterized, as understandable mistakes or oversights or experiments or whatever—how do we translate the process that we have seen at work on these relatively easy cases into the preparation of EPA or the Government in general for these tougher cases with a larger hazard?

Dr. MOORE. Senator, I would hope that the public should have some reassurance that once it was caught that it was brought to a speedy conclusion, and indeed there were penalties that were assessed.

Hopefully, the general awareness also that this action did occur in that instance should have some deterrent value we would hope on others who may be developing such data. And as I have pointed out, we have in the two other ones that were at that time pending before us, also went back and did a check of the data books that were at the two sites, to verify that indeed the data that was presented to us was done in an open and forthright manner.

I am not trying to condone the mistake that had occurred by any stretch of the imagination.

Senator DURENBERGER. No; but you have just left me with the impression that mistakes will occur in the future and as we step this up to a more complicated, more dangerous situation, mistakes are going to occur and we cannot help it.

Dr. MOORE. You know, I think that is true. Given that we are imperfect people, the best we can do is to try to have a process in place that minimizes the likelihood that such things will happen.

Senator DURENBERGER. Sir, do you draw the line someplace then in terms of hazards where you just will not even permit for a mistake? Knowing that mistakes are going to occur as the process develops, are there certain things that you just will not even consider and does the industry understand in advance that we won't even consider anything where we are taking the organism out of one environment, introducing it as a killer, and don't even come to us with those because we haven't got our processes down to the point where we can guarantee the public there's no hazard.

Dr. MOORE. I think there could be an instance where one would be concerned about the greater inherent risk associated with, say, product "X" which we haven't seen yet. If our opinion and the opinion of the experts that were looking at it was that, hey, you could allow it to go forward under this set of circumstances but be aware that this is kind of in a different category than some of the other ones you have looked at in the past. One then gets into con-

sidering that the consequence of error or the consequence of poor judgment is greater, and I think we would be more more rigorous and I base that upon our evaluation of the chemical aspects of the pesticides as well.

The consequence of error I think also has to be weighed in figuring out the rigor and the amount of data that may be——

Senator DURENBERGER. Well, maybe we can get back in later questions to how the line is drawn, because you have left me with the impression that I have to trust you because we do not have a distinct law in place. We can explore that a little bit under your authority at FIFRA later on.

But in terms of the public, they cannot be assured that there is a law in place which is guaranteed to protect them. There is in place a law that permits some judgment on the part of the Environmental Protection Agency which is not a law, it's a bunch of human beings, in which over some period of time, as any human beings, can be influenced in one way or another by those who are being regulated, which, of course, is a problem that faces people who have to rely on human judgment to implement a policy that is somewhat vague, probably deliberately vague in its application to this new industry.

Max.

Senator BAUCUS. Dr. Moore, as you well know, many Americans are concerned about foreign—by foreign I mean from other countries—animals, plants, organisms that have been introduced into the American environment which has caused problems. Starlings, for example. Not many Americans love starlings. Canadian thistle, I think, came from Russia. Spotted napre. There are lots of examples of many plants and organisms that are nonnative to America, that come from other countries which are causing various problems in our environment.

I am wondering therefore as to the degree to which EPA either is—I know it is not—but should look at biotechnologically developed organisms, organisms that we are talking about here today, somewhat the same vein as we look at—or try to prevent the introduction of nonnative species into America.

Could you tell me what you understand to be USDA policy about stopping or not stopping nonnative organisms in animals and plants into the United States, and then next I am going to ask you the degree to which any of those policies should apply to EPA or USDA or other Federal agency regulation of biotechnology organisms?

Dr. MOORE. Senator, there are going to be people who are coming behind me who are certainly more expert on USDA policy and its adequacy than I am. But let me cite an area that I do know where there is overlap and I think a beneficial overlap.

It is quite common in development, say, of microorganisms that may have pesticidal properties that one may get them from foreign sources or whatever depending on where they were first isolated. Indeed in order to be able to bring them into this country and to work with them in a laboratory, let alone before you get out into early field trials, there is a Plant Pest Act in place and in order to be able to do that you must be in possession of a permit, as I understand it, from the USDA in order to bring that into this country.

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In the review of the things that have come before us, we have shared with USDA the data that we had and they indeed have corresponded with us I believe primarily from the focus of the responsibilities they have under the Plant Pest Act and have asked particularly in the case of the Monsanto experiment EUP that we are currently reviewing, that indeed for one of the two strains that are part of the permit request that they would like to see additional data. They specified the type of data they would like to have so that one could better judge in this case the lack of pathogenicity on certain crops that they would be concerned about.

Senator BAUCUS. What I am trying to get at is given the problems we have had with these kinds of animals and organisms coming from other countries, and plants coming from other countries, I am not yet clear whether EPA's generic approach is sufficient, as you say that EPA does not look at each of these applications on a case-by-case basis, rather more generic, as I understand it. I am trying to better understand how tight the direct approach is so that the public is more reassured that that more generic approach is sufficient.

What can you tell us about EPA's generic approach to reassure us that it is sufficient to avoid the risk of potential damage?

Dr. MOORE. Senator, our current approach in the review of engineered organisms or nonindigenous organisms as well is currently being done on a case-by-case approach, and I suspect we will continue to do it on a case-by-case approach whether it will be under FIFRA or TSCA.

For the near future, until we get sufficient information, sufficient experience in hand, then indeed we might be able to draw some generic approaches to certain aspects of it.

An example that was brought to me earlier this week was that two experimental use permits that we have reviewed and granted both involve ice minus bacteria. And so the nature of concerns that were raised in the review of the first one probably allowed us with some greater degree of speed and ease to know what we wanted to look at when we were reviewing the second one.

I would assume that after we have built up a level of experience that we would more likely go to a broad generic approach.

Senator BAUCUS. Why is there so little insurance coverage of this industry in our country? I understand it is very, very difficult to get insurance. Extremely difficult. And in some cases there is no insurance. I understand that one company was offered a $1 million policy for a $400,000 annual premium. It doesn't sound very good to me. Why is it so difficult to get insurance coverage?

Dr. MOORE. Well, that is certainly far from my area of knowledge, let alone expertise. But we could ask the same question while I was here yesterday on the asbestos area where insurance is equally high. I think part of it is the liability concerns associated with a lot of things in this country, including biotechnology which appears to be somewhat of an unknown I am sure from the perspective of an insurance underwriter as to how they set their premiums. As you say, $400,000 for a $1 million policy annually, for a 1-year basis. It would suggest to me if I were out there I probably wouldn't seek such insurance.

Senator BAUCUS. One reason is because liability is unclear.

Dr. MOORE. I think so. Or the fear of liability.

Senator BAUCUS. Fear of liability is unclear. And that's part because the potential risk is also very high. Not that the risk is high, but the consequence is particularly high.

If that's all the case, then why does EPA and why do other agencies grant these applications? If these companies cannot get insurance coverage, that is, the insurance industry has made the economic judgment that it's too much risk here, if that's the case, why does EPA and why do other agencies proportionately or disportionately grant these applications more easily compared with virtual impossibility of getting insurance coverage?

Dr. MOORE. Senator, we have granted two experimental use permits. I would say in both instances that if you were to ask the people who had asked for them, they would be quick to point out that they did not think EPA granted them very easily. There was a great deal of difficulty from their perspective in what they had to go through.

Dr. Lindow has been trying to conduct his experiment for what now, 2½ years, or in that range.

Senator BAUCUS. Do you know why those companies have insurance coverage?

Dr. MOORE. I do not. The other point I was going to make as it related to insurance, some of the statutes that the Agency does have the responsibility to administer clearly mandate that indeed ability to withstand liability claims must be demonstrated on the part of the person who is going to work——

There is nothing in the pesticide statute or to my knowledge in the TSCA Statute that suggests at all that a condition of granting an EUP or a registration has to be contingent upon the possession of insurance in this case, for liability.

I would suggest that if that is something that is appropriate to require, it is probably more appropriate that Congress make that decision than EPA make that decision.

Senator BAUCUS. Just generally, what one or two or three recommendations do you have that allow greater development of biotechnology and at the same time provide more reassurance, more confidence to American people that risks in fact are minimal if not zero, and therefore enable more insurance coverage for these companies. What one, two or three major recommendations do you have? Might they include more accountability, that is, centralizing of these kinds of applications, the denial or approval of applications that are in one agency so the American public knows who is responsible here? Might that help? Or would it help if some kind of legislation might go into the insurance question here?

I am just asking you. You are closer to this. What one, two, or three most important, most significant recommendations do you have for the interests of public policy here that would enable greater development of this technology, greater confidence to the American people?

Dr. MOORE. Senator, I think first and foremost it should be a well-articulated and publicized policy on how one is going to treat and review such applications and indeed make sure that that process or policy involves the best minds that can be brought to bear on them to minimize, if you will, a poor decision as it relates to risk,

saying there was no risk when in fact one subsequently found out that risk was present.

Senator BAUCUS. Do you think that presently exists?

Dr. MOORE. I think we are trying to build toward that. Yes.

Senator BAUCUS. Sorry?

Dr. MOORE. I think we are trying to build toward that.

Senator BAUCUS. Well, it can't be there because the insurance industry doesn't believe it's there.

Dr. MOORE. I also think that something that will go as far as anything toward public confidence, accountability, or whatever, as well as the insurability, may be to let some of these early experiments finally get conducted and indeed demonstrate that the risk that some people may fear was nonexistent. I would think that might go an awful long way toward one's ability to get insurance when you have some type of a track record.

As we talk here right now, there has yet to be the first, unless Dr. Lindow is planting potatoes this morning—there has yet to be the first environmental release experiment of a genetically-engineered organism, at least a legal one I should say.

Senator BAUCUS. Do you think the state-of-the-art is sufficiently developed to determine which organisms should and should not be released?

Dr. MOORE. In the main, yes. I could also hypothesize that there may be some experiments that somebody might propose in which one would say, hey, our level of knowledge is such that we should not allow this to go forward in a deliberate environmental release.

Senator BAUCUS. Very briefly, you say "in the main, yes." Very briefly, where yes and where no?

Dr. MOORE. Obviously, as to where one could go forward these ice-minus experiments I think pose minimal risk.

Senator BAUCUS. Where is the state-of-the-art perhaps a little shaky?

Dr. Moore I would assume when you get into utilizing bacteria that are known to posess pathogenetic properties and indeed you may be or proposing a use in which you cannot make some inference of risk or safety without data to back it up.

I think in those instances what one might want to do is to suggest that the experiments of that sort be done in a contained environment to get the data. We have some of them in this country. To see if indeed you can then in a more objective fashion allow the deliberate release aspect of some of these Experimental Use Permits.

Senator BAUCUS. Thank you very much.

Senator BURDICK. Mr. Chairman.

EPA has a release application pending from Monsanto Corp. for a process to take corn root tests. Will EPA approve this application?

Dr. MOORE. I anticipate that will become publically known next week, Senator. We are in the final throes of rendering a final decision and judgment on that specific request.

Senator BURDICK. Next week we will know yes or no?

Dr. MOORE. Yes, sir. Yes, next week you will know.

Senator BURDICK. Yes or no?

Dr. MOORE. Yes, you will know next week.

Senator BURDICK. On April 25 of this year, the Scientific Advisory Panel which reviewed Monsanto's application filed a report summarizing possible dangers of releasing this microbe. The report states "In summary, a contingent protocol needed to be established as scientific credibility."

Are you confident that your prerelease review procedure is adequate so you are not counting on emergency back-up measures to rectify a mistake?

Dr. MOORE. In general, we are fairly comfortable that the decision to go, if it's a decision to go, is such that the experiment doesn't pose a risk. Again, also acknowledging the fallibility of human judgment on occasion, we have in most instances had in place some type of what I want to call a safety net or back-up system which indeed if you get a broader spread or penetration than expected that you can control it somewhat in the area.

This was true of the two ice-minus experiments and it is also true in our review of the Monsanto application.

Senator BURDICK. You know, we lawyers always use the word "reasonably safe, reasonably sure." Are you reasonably sure?

Dr. MOORE. Yes. Senator, I think you bring up a good point and that is that I think the term that the Scientific Advisory Panel has used and now the term that the Agency uses is that we think that these experiments pose minimal risk.

Senator BURDICK. All right. Is it my understanding that EPA has brought more ecologists into their review process to assess the adverse impact? How many ecologists have reviewed this particular application?

Dr. MOORE. This is the Monsanto application?

Senator BURDICK. Yes.

Dr. MOORE. Of the expert scientists that we have brought in to review, two I think would either call themselves and not take umbrage if we called them microbial ecologists.

Senator BURDICK. Anyway, there were two?

Dr. MOORE. Yes.

Senator BURDICK. Does EPA have a streamline application and oversight process so that all companies are subject to the same procedures and scientific evaluation?

Dr. MOORE. Yes; I think we can clearly articulate and have articulated a policy that has general application for the review of anything that's going to come in as a pesticide under FIFRA. I would also say that process is essentially analogous to that which we will use when and if we ever get our first submission under the Toxic Substance Control Act.

Senator BURDICK. Now, some of us lawyers and some of us ordinary citizens have trouble with a lot of these new phrases. Would you provide for the record EPA's definition of the following term: genetically engineered organism, recombinant DNA organism, release and containment. Put that in English.

Dr. MOORE. Yes, sir.

Senator BURDICK. Thank you.

Senator DURENBERGER. Thank you, Quentin, very much.

John, let me ask you a little more specifically the kinds of questions that Senator Burdick was asking you. Can you tell us techni-

cally what Monsanto is proposing to do? What kind of genetic manipulation did they make and how will it be applied?

Dr. MOORE. Senator, they took two strains of bacteria from one of their test sites in Missouri so it was a natural organism they took out. They brought it into the laboratory. They then basically took that organism and inserted a genetic sequence that was derived from an already registered microbial pesticide called Bt or Bacillus thuringiensis. What they took out of that Bt organism was that gene piece that produced the chemical substance that controls caterpillars——

Senator DURENBERGER. Bt is a——

Dr. MOORE. Registered pesticide.

Senator DURENBERGER. Yes; and that's a toxin?

Dr. MOORE. It is a microbe that secretes a toxin that basically will control things such as cabbage worms and other worms. It also controls tomato worms, things of that sort.

Senator DURENBERGER. So what are they going to do with it?

Dr. MOORE. They took from the Bt organism that part of the genetic code that made that organism produce the chemical that did in the tomato worms, and inserted it in the sutamonis bacteria they had got out of the soil from their test farm in Missouri.

Their request of us is that what they would like to do is conduct experiments on a test plot whereby they would take this organism and treat corn seed immediately prior to planting and then conduct their experiment. Plant their corn and have the corn grow. Their hope is to see that this sutamonis organism, which has now been engineered to have this Bt toxin in it, will colonize the root zone of the corn plant.

Senator DURENBERGER. Will do what?

Dr. MOORE. Colonize or live.

Senator DURENBERGER. Colonize.

Dr. MOORE. Live in the root zone of the corn plant.

Senator DURENBERGER. Live is a better word.

Dr. MOORE. Yes; live there. And secrete——

Senator DURENBERGER. They are going to put it in the seed corn——

Dr. MOORE. Put it on the seed so as the seed sprouts and develops its roots, hoping these bacteria will go along with the root system. And if they do live there, will they secrete this toxin into the soil and therefore control some of the natural worms that live in the soil that typically have an adverse effect on the growth of the corn plant.

Senator DURENBERGER. Then the corn plant grows from the seed?

Dr. MOORE. Yes.

Senator DURENBERGER. And the microbe that was in the seed will live in the soil?

Dr. MOORE. Yes.

Senator DURENBERGER. From the seed to the root out into the soil?

Dr. MOORE. Yes.

Senator DURENBERGER. And it lives in the soil. And in that soil also live other litle——

Dr. MOORE. Things you don't want.

Senator DURENBERGER. Stuff that Max was talking about earlier, the bad guys.

Dr. MOORE. Yes.

Senator DURENBERGER. And they normally would attack the corn plant? Is that right?

Dr. MOORE. Yes.

Senator DURENBERGER. OK. So what are they going to do? What effect will the microbe have on these worms?

Dr. MOORE. Hopefully, this microbe that is living along the roots of the corn plant will secrete a chemical that as these other undesirable worms come along, it will produce sufficient quantities of chemicals to do them in.

Senator DURENBERGER. To kill them?

Dr. MOORE. Yes.

Senator DURENBERGER. OK. Now, tell us a little bit about the life of the toxic microbe. So it's out there in the soil, killing worms. What else will it kill and how long will it live? I think that's what we are concerned about, isn't it, as we get into this area?

Dr. MOORE. Yes; we are getting into the heart of what is actually being looked at as part of the data set in determining whether I am going to allow the experimental use permit to go, and that is, will it persist out there, and if so, in what quantities? In addition to living on the roots of a corn plant, where else might it find a home that it likes to live, and if there are other places, what does it do, what doesn't it do, depending on which way you want to say it?

We also want to have some indication that in addition to maybe producing an adverse effect on those soil worms we don't want, what else might it be pathogenic to or cause adverse effects to? And so we require data to support the——

Senator DURENBERGER. Does Monsanto give you in advance some indication of how long they think the life of this new microbe will be so that you can say, well, we can leave out a whole set of effects because it doesn't last more than 1 month, 2 months, given the nature of the soil, the water, et cetera, et cetera?

Dr. MOORE. Yes; and we would require data that would suggest how many would survive, what's the length of survival, will it disperse, will it leave the corn roots and go elsewhere? And if so, where? Is it passive? Does it cause adverse effects to, obviously not the corn, but to other plant species? To other insect species? Which is probably the major concern.

Senator DURENBERGER. Right. Do you have people on your staff to look that over and, say, they are right, or they are wrong, or something like that?

Dr. MOORE. Our initial analysis will be done by staff within the Pesticide Program to form those opinions. What we in essence are doing with an outside expert group, we are letting them have the same data the Pesticide Program has. They also are receiving a copy of our draft analysis of what we think this data submission says and what concerns we have or lack of concerns we have. So the outside experts can read the original data, draw their own conclusions, and then also look at what we have summarized and see what we have interpreted, and see if they agree with us or disagree with us. And we see if we end up with a consensus as to what are

areas of concern, and if so, discuss the degree of concern that might be associated with those areas.

Sometimes it comes out to say, well, we would like to have more data on this particular point before we render a final decision. That, for example, is what happened in the Lindow experiment. When he first said that he wanted to conduct this field test, we wrote back and said he would have to go through a formal EUP. We also identified additional data we would like to have him submit when we review it. He generated and provided that additional data.

Senator DURENBERGER. Are you pretty close to issuing a permit in the Monsanto case?

Dr. MOORE. We are close to rendering a decision on the Monsanto application. I will probably announce it next week.

Senator DURENBERGER. Next week?

Dr. MOORE. Yes.

Senator DURENBERGER. OK. So it's been through your science advisory panel and all the things you've been describing. Now, are there some judgments someplace that go on in this process? I don't want you to tell us the conclusion, but describe the process.

Dr. MOORE. Senator, we have the original interpretation of a series of agency scientists that review all of the Monsanto data. We also have comments that we receive from USDA and other sister agencies. We also have some outside public comments that we have received. And we, of course, have the review and written comments of the expert science panel that also review the data. I think it's a collation of all of that information that is now being factored in leading to a final decision as to whether it's go, no go, or go with conditions, or anything else that——

Senator DURENBERGER. Well, then, your bottom line, you will say to us and the public and to the applicant, there is no significant risk involved in this experimentation in our judgment as long as they meet some satisfactory criteria which they have agreed to. That is sort of the bottom line?

Now, let me ask you about what factors contribute to—again, you can do this in the abstract, if you want. Or in the specific if it facilitates the answer. But what are the factors that contribute to the judgment that no significant risk is posed by an experiment? And what I'd like you to do is talk to us about how much of your judgment is affected by the experimental nature of this proposal? How much of it is affected by the scale of the proposal? How much of it is affected by the fundamental nature of the genetic engineering that's involved?

Dr. MOORE. Typical types of information that we review, and therefore factor in in making a determination are basically, obviously, what is the organism? What is its natural habitat? What is the host range? You know, it might prefer to live on cauliflower, to pick a hypothetical example. But under some sets of circumstances, it might also live on a tomato plant if there isn't a cauliflower plant around. I mean it does have maybe secondary preferences or things like that.

Senator DURENBERGER. Host and home? I mean, where it is going to make its home?

Dr. MOORE. Yes.

Senator DURENBERGER. Where this microbe is going to make its home.

Dr. MOORE. Right. What effects might it have on these organisms or plants in my hypothetical example? Will it grow? Will it reproduce? Will it survive even if it doesn't reproduce? And in effect, what I want to say since we are talking about pesticides here, what effects might it have on what we call known target organisms?

Monsanto is developing this thing to see if they can control corn root worms, for example. What effects might it have on other types of worms beyond the corn root worm or other types of organisms?

This is the type of information that we want data on that has been developed in a laboratory to render the judgment that, in addition to affecting the host which you hope it will affect, it doesn't also extend to other areas as well.

A key question has been, for example, on the two ice-minus experiments was survivability. The expert opinion is, and there is data to back this up, that this organism will survive in the environment. It isn't like it will just have a finite lifespan. It will survive. It will reproduce. However, the data suggest it has no competitive advantage, whatsoever, over the natural ice-minus and ice-plus organisms that already existed in nature. So if this organism that we have engineered gets there first, gets to sit on the strawberry bud first, it is probably going to stay there and when the natural ice-plus or ice-minus comes along, since somebody got there before them, so to speak, it is not going to find its place. It won't displace it. It doesn't have the competitive advantage of coming in and if a natural one got there first of pushing it away, of saying, you know, theoretically, "I win."

But it is going to survive. The consensus of opinion is that it will survive.

Senator DURENBERGER. Would you agree, I have got to get to the bottom line here, and then we will finish this up. Would you agree with me that the Monsanto decision is fundamentally different in character from the ice-minus and the swine vaccine proposals?

Dr. MOORE. Let me stay with the ice-minus, because it is something I know about. They are certainly different. Both of the ice-minus experiments involved primarily application or growth on the vegetative portion of the plant. Now, Monsanto by comparison is involved in this case with the root zone of a corn plant. The ice-minus experiment is by its nature—we took a piece of genetic information out of the ice-plus, so it no longer could make a certain type of protein.

In the case of the Monsanto application, we took a piece of genetic information and added it to the bacteria that is going to go into the zone.

And so those are the two main differences. Deletion versus an insertion and certainly locale is different. And in the Monsanto circumstances, you are producing a toxin, whereas in the ice-minus case, you have a bacteria that will fail to secrete a protein which allows ice to crystalize around it.

Senator DURENBERGER. Let me just say at this point that I have a wide variety of other questions that deal with the role of State government, local government; with the existing authority under FIFRA, and some of the possible authority under TSCA. I would like

your reactions now that you have had some time to think about it. I will submit them to you.

I will also say that the Monsanto Co. was invited to be here today and I wish they had been only because I think this, like the other hearings that we have held, have been primarily educational. I think those who have had the opportunity to be here and watch this through other mediums have probably learned a little bit more from your openness and your honesty in being responsive to questions. I think at this stage of the game that is what—at least from this subcommittee's standpoint—that is what these hearings are intended to do. To educate all of us and to lead us in the direction of the most appropriate relationship between the society in this country and its Government, and the authority which it has to protect that society, and a very valuable and vital industry that is growing in this country. And maybe next time Monsanto will be, and others, will be more willing to participate in these sessions.

Max, do you have any other questions?

Senator BAUCUS. One other question.

Mr. Moore, as I understand it basically you look at these applications and try to determine whether there is a significant risk. And if there is no significant risk, you approve them.

Now, there are some who say there is risk and there is risk. That is, the question is not so much whether there is a risk of some potential harm. But rather the risk is that if there is potential harm, the risk of the magnitude of that harm is too great. That is to say that perhaps the regulatory approach to this question should not be the approach of what the present statute has. But rather should be more in the nature of how we regulated the nuclear industry in the past. There have been problems there. We all know of the problems. Nevertheless, the thought is that the least of a harmful microorganism environment is much like the least of radioactivity in the environment if there is a mistake at a nuclear site.

The same vein that the microorganism is released to the air, a harmful one, when it's done, it's in the air somewhere. The winds carry it. Who knows where it might go. The same with radioactive clouds and we all know Chernobyl results are felt over here in our country.

I am just curious what you think about that approach. I mean, the thought is maybe we should be tougher on containment because it is a low risk but high significant risk. That is, there is lower probability that something harmful might happen but if something harmful happens, the magnitude of that harm is potentially much greater than is the case where there is harm to the environment under other statutes. I am just curious what you think about that.

Dr. MOORE. Senator, our approach, I think, fits in with what you are asking me in your question and that is we have particular concern about a living organism that is going to be released into the environment as opposed to a living organism that might be in a fermentation vat or something like that, where it is closed, it is contained, when you are done with whatever it is you want to do, you basically can kill the organism by sterilization or steam or some sort or another.

So I think the particular concern has to be with living organisms, living organisms released into the environment. The degree of scrutiny and the amount of data that one would like to have before allowing that to occur is certainly far more extensive than in a contained circumstance.

I think there is another point that is I believe very important in this case using FIFRA, which I think is adequate to the purpose. And that is in the two instances that we have allowed to go forward, and I believe it would also be true of any of the ones that I can see coming in the foreseeable future, we said "you can go forward and do that experiment that way on that site" and in the case of AGS, "once." And that's all. We were very definite in what we were going to allow that could be done.

In a similar vein, the experiment that we approved for Dr. Lindow was a series of somewhat the same experiment over a period of time, but it was very definite what he was permitted to do.

The reason for that is we want to use the data that is going to be generated by that experiment as a basis for making hopefully more objective determinations for any future experiment he or others might want to propose for these organisms.

Senator BAUCUS. I think the argument is that because of the nature of this animal, because it is more in the nature of a radioactive emission, that is, something harmful, an organism is released, that probably explains why it is not covered by insurance. That is, the potential magnitude of an adverse consequence is so high. Even though the potential of something harmful happening is low. Suggesting perhaps that a new approach should be taken here. I don't want to carry this now too far. There are lots of problems of analogy, I grant you. Many. But at least when we developed the nuclear industry, there were lots of very tightly contained experiments. And maybe there has to be very tightly contained experiments in this area before we go to the next steps.

It is just a thought that occurred to me, frankly. I don't want to pursue this too far, but I wonder what your reaction might be.

Dr. MOORE. Senator, people within the industry could be much more eloquent on what I am going to say than I can. But I do know that there is some thought being given that certain types of things that may be produced, in addition to putting something in a microbe that you might want, you might also have an effect that could be of concern if it went unchecked.

You also could put in another sequence which basically has a suicide trait that is associated with it. One thing that I know is being looked at is that one might put in a heat sensitivity built into that organism, so that under the conditions of proposed use, its ability to do whatever you want it to do is there and then due to the heat limitations that you also built in elsewhere in the organism that once it gets above or below a certain temperature it basically dies.

I refer to it as a suicide trait.

Senator BAUCUS. I have a letter dated May 12 to you basically from the group opposing the Monsanto permit. Basically saying that in Charles County, there are zoning problems. I am just curious specifically what effect that problem is going to have on your decision.

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Second, what general recommendations do you have about zoning problems as they are calculated into your decision or other agencies' decisions as to whether to proceed or not?

Dr. MOORE. The Agency's position has been and I think will continue to be that as it relates to FIFRA, we will issue, say, an experimental use permit or register a pesticide, but that indeed a State or a political entity within that State can develop more stringent requirements beyond that.

Senator BAUCUS. What happens when the zoning laws prohibit this activity?

Dr. MOORE. I think this is something that we are going to have to—not just EPA, but we as a society are going to have to watch. If indeed as a consequence of local zoning concerns or whatever the type of mechanism, you essentially prevent all of these experiments from occurring——

Senator BAUCUS. I agree, but in this case are you going to do something which violates the law?

Dr. MOORE. No; I think—whether in this case—I assume it is St. Charles, MO, that has sent this in.

Senator BAUCUS. Yes.

Dr. MOORE. But whether or not they have a zoning requirement or not I don't think will factor into our decision to grant that experimental use permit to Monsanto in this case because we obviously grant it with the understanding that they also have to be in compliance with State and local jurisdictions as well.

For example, in the AGS experiment, which we approved, which was going to be done in California, the State of California also had a requirement that they had to issue a permit in that case.

Senator BAUCUS. Thank you.

Senator DURENBERGER. Senator Burdick.

Senator BURDICK. Mr. Chairman, in view of the hour, I would like permission to file questions for these witnesses today.

Senator DURENBERGER. I think we all have some questions.

Jack, thank you very much for your testimony. We appreciate it a great deal.

Next, may I call the next two witnesses, Orville Bentley, the Assistant Secretary for Science and Education, Department of Agriculture, Washington, and Alan Tracy, Assistant Secretary for Marketing and Inspection Services of the Department of Agriculture in Washington, DC.

Gentlemen, we appreciate you being here. Your statements which we have will be made part of the record and you may proceed to summarize those statements in as brief a period following Jack's example.

STATEMENT OF ORVILLE G. BENTLEY, ASSISTANT SECRETARY FOR SCIENCE AND EDUCATION, DEPARTMENT OF AGRICULTURE

Mr. BENTLEY. Thank you, Mr. Chairman.

Mr. Tracy and I personally and the Department of Agriculture appreciate the opportunity to meet with the committee and share

62-307 0 - 86 - 2

information that we have and in the area for which we have responsibility with regard to biotechnology.

I will really have comments and it will be in three parts. The first part I want to talk about are some overall developments in policy initiatives in the Department of Agriculture that not only establishes a Departmentwide framework for looking at these issues, but it provides the mechanism whereby we again interact and be a part of the governmentwide activity that is underway for coordinating guidelines for regulation and experimentation with biotechnology under the auspices of OSTP.

This initiative started, as you know, with the issuance of a policy statement in December of 1984 by OSTP in which it outlined a general approach that would be followed in developing guidelines for regulation.

I would say in the Department of Agriculture we share enthusiastically the opinion you expressed earlier at the outset of this hearing about the potential and the opportunities that might be accorded to us through the application of electrobiology or biotechnology to food and fiber production, working with the control of diseases, insects, and so forth.

We also proceed under the assumption that many of the products that may come from the application of this technology will be fundamentally similar or not different fundamentally that is from conventionally produced products. And that we feel their framework for regulation is adequate for biotechnology as it applies to food and fiber.

We say that because by sake of illustration if one modifies a major crop plant, the plant will be essentially the same. That is, we will try to introduce disease resistance or drought tolerance or more vigor into the plant to cope with environmental stress.

Since the initial publication of the OSTP report, there have been a number of actions taken in USDA relative to funding research projects, and the regulatory agencies working with the commercial development of these products, but we have been mindful throughout all of this of the questions concerning human health and the environment as we apply our existing statutes to these activities. And we are, of course, sensitive to the perceptions or questions of that that have been raised and throughout the comments made by our colleague, Mr. Moore, and by the questions that are raised by the committee.

In this line, Secretary Lyng established an Office of Agricultural Biotechnology on April 19. This Office would be responsible for implementing and coordinating the Department's biotechnology policies and procedures, including the conduct of laboratory and field research, experimentation on biotechnological products prior to their commercialization, and all matters of oversight of biotechnology in agriculture.

This Office would report to the Assistant Secretary for Science and Education. It is intended to serve as a role in providing checks and balances and communications of our activities within the Department.

It also sets a framework for advisory committees that would consist of people from not only the Federal appointees or employees,

but people that might be drawn in from the public and private sectors to provide an advisory capacity.

It should be clear though in all of these activities, while we are speaking of research, that the Assistant Secretary for Marketing and Inspection Services will continue to exercise the Department's regulatory responsibilities for licensing products developed through research whether it comes from the public or private sectors.

To this end, the Secretary issued a memorandum on July 19, 1985 in which he delegated the authority for coordinating the development for carrying out of all matters and functions pertaining to the Department's regulation of biotechnology to the Assistant Secretary for Marketing and Inspection Services. And he further delegated the responsibility to the Administrator of APHIS, the Animal and Plant Health Inspection Service, and in the same memo delegated responsibility for coordinating the development of all matters relating to USDA-funded agricultural research to the Assistant Secretary for Science and Education.

Just a few comments concerning this allocation. The responsibility for research would be primarily those agencies, the Agricultural Research Service, the Cooperative State Research Service, the Extension Service, and the Office of Grants and Program Systems.

Then likewise, the Assistant Secretary for Marketing and Inspection Services oversees regulatory activities of APHIS, the Agricultural Marketing Service and the Food Safety and Inspection Service.

So that decision relative to the organization has been done and we are now in the process of working to carry out these responsibilities of the Department in the interest of public safety, but in the interest of helping to encourage the development of biotechnology and its application to agriculture.

We are sensitive to a number of concerns, one of them being the matter of confidential business information or the CBI and that's of concern to the industry as we work with them and we will be taking the precautions and steps that are required to fulfill that obligation for the Department.

I want to make just one more reference to the fact that we are participating in the development of a statement on research and regulation of biotechnology in the Federal Register and, as you know, there are similar statements being prepared by NSF, FDA, EPA, NIH, and OSHA and we will be participating fully in these activities.

The USDA policy includes a description of the proposed new regulations under the authority of the Federal Plant Pest Act and the Plant Quarantine Act for genetically engineered organisms which are plant pests.

The USDA, pursuant to the FPPA and PQA, regulates the movement into and through the United States of plants and plant products, plant pests, and any products or articles which may contain a plant pest at the time of the movement. These articles are regulated in order to prevent the introduction, spread or establishment of new plant pests in the United States. The regulation proposed by APHIS for regulation of genetically engineered organisms would require a permit prior to the release into the environment of a genetically engineered micro-organism which presents a risk of the

introduction, spread or establishment of a plant pest. Permit requests would be filed with USDA, APHIS, Plant Protection and Quarantine.

Also explained in the USDA policy statement are the procedures APHIS follows in licensing veterinary biologics regulated under the Virus-Serum-Toxin Act of 1913 which may be derived by recombinant DNA techniques or developed from hybridomas.

As you know, the Virus-Serum-Toxin Act of 1913 provides authority for APHIS to regulate all veterinary biologics imported into the United States or shipped or delivered for shipment interstate. The recent amendments contained in the Food Security Act of 1985 have extended this authority to products which are shipped intrastate or exported, and have given USDA additional enforcement mechanisms such as the power to detain and seize products.

Under the VSTA, veterinary biologics may not be sold, shipped or delivered for shipment if they are worthless, contaminated, dangerous or harmful.

The Secretary now has the authority to regulate the distribution of all unlicensed biologics subject to statutory exemptions when shipped interstate or intrastate.

Prior to recent VSTA amendments, USDA authorization was required for intrastate distribution of experimental, unlicensed biologics. Regulations are now being prepared by APHIS which will extend these requirements to intrastate movements as well.

For the purpose of licensing, biologics derived by recombinant DNA techniques or developed from hybridomas may be classified into three broad categories based on the biological characteristics of the new products and the safety concerns they present.

Senator DURENBERGER. Mr. Bentley, are we getting sort of close to the end of the statement?

Mr. BENTLEY. Yes.

Senator DURENBERGER. Thank you very much.

Mr. BENTLEY. On the next page I do list a few of the provisions of the three categories. I will not go into those, but they are a part of the record.

The other comment that I would want to make has to do with the question on the pseudorabies vaccine and in my statement I have a full comment about the activities taken by the APHIS in reviewing this proposal and licensing the OMNIVAC, a genetically engineered pseudorabies vaccine which has been categorized as one of the products that gets into the review by the APHIS procedures. This license was issued pursuant to the regulations that are referred to. A 2 week voluntary suspension was agreed to by the Department and Tech America to permit USDA to provide full documentation describing the analytical steps that had been taken to ensure that the product was environmentally safe. This review showed there was no significant environmental impact.

Some brief comments about the Science and Education. We are reviewing the plan. As we outline it, will be one developed basically parallel to those that have been successfully used by the NIH-RAC and established under the NIH guidelines. And all Federally funded agricultural biotechnology research, conducted in an institution receiving USDA funds, will be subject to these guidelines, and we would expect that there would be some private institutions

that would want to request the use of these existing guidelines as well.

We believe that the establishment of the Office of Agricultural Biotechnology and the pending publication of the Federal biotechnology policy statement will alleviate any confusion which has existed and will help us in handling issues that will come before us whether it be in research or in project licensing.

We would be pleased to answer your questions.

Senator DURENBERGER. Mr. Secretary, thank you very much.

Do you believe that the laws under which you operate give you sufficient authority to deal with all of the organisms that you should review before release or do you have in mind that there might be some classes of organisms that you cannot reach that maybe you should reach but you don't have the authority to do that?

Mr. BENTLEY. At this time I think that there are existing authorities that will give us the opportunity or will provide us the statutory capability to regulate those. Now, there might be organisms that would emerge or the kinds of organisms to be developed that we cannot. However, I do want to point out that many of these decisions, of course, are going to be science driven. That is, we are going to consult widely. We are going to rely not only on advisory committees that develop internally where we have a great deal of expertise. But that we will have the capacity under proper sets of conditions to call on scientists throughout the university system to help us make decisions there. That is our pledge. We are going to be prudent and careful in this area.

I would just add one additional caveat. I think it is important to us to have good communication with other agencies that have responsibilities. For example, for us in biology in the research area we would certainly look to the experiences of the NIH-RAC where it goes back over some 8 to 10 years.

Senator DURENBERGER. In listening to your statement you talked about your overview of university-based research.

Does your policy treat those who do research with public funds differently from those who are doing the same research in the private sector?

Just by way of an example, would Mr. Kitt, who is associated with the swine vaccine case, would he have been required to seek a license for his vaccine activities if he had been doing research in the private sector rather than in a university setting?

Mr. BENTLEY. Yes. He would be required before—I turn to my colleague here—yes, he would be required to get the license before commercializing the products.

Senator DURENBERGER. You do not make a distinction then between research funded in a public setting or with public funds versus a private setting or with private funds?

Mr. BENTLEY. There could be minor exceptions in here, but regardless of where the research if the research—was done in the public sector and that led to a product and the product, say, was being commercialized and so forth, yes, it would go through review and licensing, would be subject to the same review in licensing as would be——

Senator DURENBERGER. Mr. Tracy.

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Mr. TRACY. I think it is important to distinguish between the research side and the regulatory or licensing side. For instance, under the Virus-Serum-Toxin Act, we have various other acts too, such as the Plant Pest Act. But under VST what is required is that the safety effectiveness, purity and potentency of the proposed vaccine or serum, toxin, be proved. That treats all applicants equal on the regulatory side.

On the research side, there is a difference as to whether it is publically funded or not as we do have, under the NIH guidelines, the ability to withdraw funds from a university or from the body which is receiving Federal funds and which does not comply with those guidelines.

Senator DURENBERGER. One other question. There has been some concern expressed by the General Accounting Office, among others, about the organizational structure at USDA as it applies to review and regulation of biotechnology and in your testimony this morning, Mr. Secretary, you indicated that there is reorganizing going on, but at least to me the new structure still sounds somewhat complicated.

Isn't there, in your opinion, a real need to bring everything under one tent, as I might say, to make sure that things get accomplished in a more orderly or a more confident way? I think about your experience in reviewing those two tobacco plants proposals. It is at least my impression that the proposals went to two different offices in your Department, and that neither one of them has been processed as of yet. Is that an incorrect impression? Then give me your overview of the one-tent proposal.

Mr. BENTLEY. That's our goal is to bring more things together, and coordinate our activities. The Department of Agriculture has a unique arrangement. It has a research component, if one uses NIH as an example, National Institutes of Health. And we also have the responsibility for regulatory, and these have opportunities for certainly coordination and communication as to what is going on. That's what we hope to achieve through this office without creating a bottleneck or another administrative layer.

And that I think we can do and I think we are acting on it. The Secretary has asked us to this and we are going to and I think we can.

Now, the question on whether proposals come to different agencies, I think that this——

Senator DURENBERGER. Do you know about these tobacco plant proposals I am talking about?

Mr. BENTLEY. Yes. The modification on tobacco, the insertion of a gene, and I think you are probably referring to the Calgene proposal. That's one that I've heard about that we have. And that is being processed and it is being reviewed by the Scientific Advisory Committee. The matter now is having to do with whether the application of the EA or the Environmental Assessment impact and so on.

That there was confusion on this, we think that we want to take steps to eliminate that so that when a proposal comes to the Department of Agriculture that we handle it effectively and get it to the appropriate agency so that it is not necessary for people to "shop around."

Senator DURENBERGER. I don't know why we experiment on tobacco, but now that you have got two of them out there what stands in the way of bringing them together?

Mr. BENTLEY. Well, I think they have been brought together.

Senator DURENBERGER. They have been brought together?

Mr. BENTLEY. Yes, they have been brought together. There is some information. I think the status of that, and I am not precise exactly, but there is some additional information that the company will need to submit before the application can be further processed, and that is where we are at the moment.

Senator DURENBERGER. Sort of as an aside, do you have in your bailiwick in Science and Education, are we doing pure research in the Government on tobacco or——

Mr. BENTLEY. There is a research program. It is about the $3 to $5 million range that is being done on composition of tobacco, a somewhat limited program, but there is a program on research in USDA. Of course, there is research at experiment stations throughout the country on tobacco.

Senator DURENBERGER. What is the objective of that research?

Mr. BENTLEY. The major thrust of the research being done in the USDA and ARS has to do with composition of tobacco and finding all the various components in it and finding out what happens to them during the smoking process or the processing of tobacco. That is primarily what we are looking at.

Senator DURENBERGER. And to what end?

Mr. BENTLEY. The end will be to find out whether or not we have a full understanding of the possible harmful chemicals that are in tobacco. And if we know what they are—we started out just knowing about a small number, I don't know, less than 50 perhaps, and now we have found that there's up over 500 or 600 compounds of various kinds, but many of them in very small amounts. But we are finding out about it and then we can use some of the new modern technology and laboratory methods to analyze it.

Senator DURENBERGER. Is there similar research going on in other Departments of the Federal Government on the effects of tobacco?

Mr. BENTLEY. I am not aware of any, no. Well, smoking and health are questions at NIH, but I don't know what they are doing, but growing tobacco is still a profit for several areas of the country.

Senator DURENBERGER. Is research being done at the University of North Carolina or places like that? Where is it being done?

Mr. BENTLEY. Well, University of North Carolina, State University, has done a lot of work with tobacco.

Senator DURENBERGER. With Federal money?

Mr. BENTLEY. Well—and North Carolina.

Senator DURENBERGER. Senator Baucus.

Senator BAUCUS. Mr. Secretary, I understand that Calgene has asked to have its application suspended. It's lack of confidence of procedure at USDA. Is that understanding correct or incorrect?

Mr. BENTLEY. I think they asked, and they did this by the fact that they said they wouldn't be submitting some information.

Senator BAUCUS. I'm sorry?

Mr. BENTLEY. They did that by saying that they thought they would delay in submitting additional information which was being

required. However, we are talking and they are talking with us, and I just don't know. It's in a limbo status right at the moment.

Senator BAUCUS. So it is true that they have in effect asked for suspension of its application?

Mr. BENTLEY. Well——

Senator BAUCUS. Pending greater confidence in the process of USDA.

Mr. TRACY. I Understand that the company has submitted a letter where they asked for this delay, not a withdrawal of their application.

Senator BAUCUS. As I said, suspension.

Mr. TRACY. Delay. I am told they are willing to have that letter available.

Senator BAUCUS. I'm sorry?

Mr. TRACY. They are willing to make that letter avail- able to you.

Senator BAUCUS. The company is?

Mr. TRACY. Yes.

Senator BAUCUS. Willing to make its letter as to its suspension available?

Mr. TRACY. Right.

Senator BAUCUS. So it is true that the company has asked for a delay——

Mr. TRACY. A delay.

Senator BAUCUS. Why has the company asked for a delay?

Mr. BENTLEY. I would like to impart that they would like to await the publication of the total guideline package for biotechnology regulation that is now in process under the aegis of OSTP. That is part of the reason, so they are sure of the published procedures in its compliance with that.

Senator BAUCUS. Do you think its concerns are justified?

Mr. TRACY. I haven't seen the letter. I assume it speaks for itself and gives the reason.

Mr. BENTLEY. It gives essentially what we have talked about here as their reasons.

Senator BAUCUS. Obviously, it seems like this is the case where a company does not have full confidence in the procedures of the agency and therefore elected to see at this point. It's further obvious that this is something that USDA should clear up so that not only Calgene but other companies don't face this kind of problem.

Mr. TRACY. It is true that something new is going to happen. And are going to have a new Federal policy statement which includes policy statements of various agencies, including USDA and we expect these to be available to the public in the very near future.

It is also true that at the time that policy statement is published there will be a proposed regulation, a new proposed regulation, under the Plant Pest Act. And they may want to see that proposal to determine whether it might affect their application.

Senator BAUCUS. How many different applications has USDA received of this nature, say in this year, 1986 roughly?

Mr. TRACY. Of this nature?

Mr. BENTLEY. Of the nature of the tobacco case, there is really only one that we are processing. But you have to keep in mind, we are in a period of transition from getting the established proce-

dures together and we have been spending a lot of time on that, on an interagency basis.

Senator BAUCUS. There is only one. I am a little concerned that you don't know very much about the status of their——

Mr. BENTLEY. I will be glad to give you a complete statement on the status of the Calgene. It has been reviewed by the Science Advisory Committee, and I believe the recommendation is that it doesn't create a risk and so forth, given the protocols that the company will apply, and at the current time the question has to be whether or not research proposals of that type are subject to the requirement of NEPA and that's one of the questions we are raising and that's been a question that is still being debated and at this time the company has said they would delay the proposal but they wanted to talk with us about it as to whether they should move ahead.

Senator BAUCUS. When will your new policy statements be published? By what date?

Mr. BENTLEY. Well, this is published under the aegis of OSTP. It is hoped that this proposal will be reviewed by the Domestic Policy Council this next week, and it is hoped that publication will be shortly. The reason I qualify it is that we had thought and had hoped that we would have this before, but at this time I think it is in the near future. I hope in the next couple of weeks.

Senator BAUCUS. Can we count on 3 weeks?

Mr. TRACY. It is not in our hands.

Mr. BENTLEY. It is not in our hands.

Mr. TRACY. It is being handled by the White House, Office of Plans and Technological Policy. They've had it on the schedule a few times but it's been put off.

Currently it's on schedule for this week. We certainly hope that it goes ahead.

Senator BAUCUS. Can't you go over there and sit on them?

Mr. TRACY. We've had a lot of conversations with them. It is unlikely to be delayed much more.

Mr. BENTLEY. The material from Agriculture has been submitted, but I want to commend OSTP for their efforts, and the Biotechnology Working Group. It's been over 2 years now. It brings together several agencies. It involves reaction from Commerce, Department of Commerce, and Justice and other Departments, and certainly it ties in with OMB, so there's a lot of review of the policy and there's many parts to it. There are some complicated things that would take too much time to go into that are much more difficult to resolve than we thought they were.

Senator BAUCUS. I understand that. Obviously it's a new area.

Mr. BENTLEY. It is a new area.

Senator BAUCUS. It's a new area, a new arena. It is all new to everybody. But I also get the feeling it's a little fouled up. And I just encourage you in ways you can to straighten some of this out a little bit better than it seems to be.

Mr. BENTLEY. Senator, I feel I share the frustration because I myself and members of our staff have worked a lot of hours trying to resolve some of these questions, and that is going to be our goal.

Senator BAUCUS. Sometimes you have got to get a little tough. You've got to raise a little hell; there are different ways to skin a cat around here. You've got to be resourceful and get the job done.

Mr. BENTLEY. Yes.

Senator BAUCUS. Thank you.

Senator DURENBERGER Mr. Secretary and Mr. Tracy, thank you very much for your testimony.

Now, our final witnesses are Margaret Mellon, the director of the toxics program of the Environmental Law Institute and Dr. Alan Goldhammer, the director of the technical affairs, Industrial Biotechnology Assocation, Rockville, MD.

Your written statements will be made part of the record and you may proceed to summarize those statements in 5 minutes each beginning with Ms. Mellon

STATEMENT OF MARGARET MELLON, DIRECTOR, TOXICS PROGRAM, ENVIRONMENTAL LAW INSTITUTE

Ms. MELLON. My name is Margaret Mellon. I am the director of the toxics program for the Environmental Law Institute. I have been asked here today to comment on the legal adequacy of the statutes administered by the USDA as a basis for the regulation of genetically engineered organisms.

I have just finished examining the statutes for a treatise chapter I am writing and my conclusion is that the statutes are inadequate. They do not provide a sound statutory foundation for an effective program to review engineered organisms prior to their release into the environment.

I have with me an analysis of the statutes which I will provide to the committee but will spare this audience. Instead, I would just like to summarize what I believe are the statutes' three major legal deficiencies.

The first is inadequate coverage. The current scientific view is that all novel organisms, plants, animals, and microbes, pose threats of ecological disruptions. Yet the agricultural statutes, even taken all together, do not give USDA authority to regulate all kinds of organisms.

The statutes, the most important of which are the Plant Pest Act, the Noxious Weed Act, and the Virus-Serum-Toxin Act, each cover a group of organisms restricted by use, for example, as a toxin or a vaccine, or by some property. It must be a plant pest or a noxious weed.

The result is a crazy quilt of coverage that leaves out several categories of organisms that might constitute ecological hazards. Among these are noninfectious agents of animal disease, crop plants themselves, and organisms beneficial to plants.

It is important to note that from the environmental point of view, an engineered lady bug, although beneficial to garden plants, has as much chance of upsetting the ecological balance as an engineered Japanese beetle.

Second, these statutes' lack of authority to conduct prerelease review. Except for the Virus-Serum-Toxic Act, the agricultural statutes do not provide explicit authority for a prerelease review of organisms. The Plant Pest Act and the Noxious Weed Act are often

referred to as remedial statutes. These statutes limit interstate movement and importation of organisms already known to be plant pests or weeds. The statutes give USDA broad power to inspect, to seize, or to destroy organisms or vectors of such organisms to require permits for their transport once they know that the organisms fit the definition. But they do not explicitly authorize or require the testing or review of organisms to see whether they fit the definitions.

As the Plant Pest and Noxious Weeds Acts are currently being implemented, there are no programs testing organisms prior to their release to see whether they are, for example, plant pests. By that I mean there is no routine submission of data, no base set of data required, no time limits, no standards for decisions, and no recourse available to manufacturers or to environmental groups dissatisfied with agency decisions.

It is possible that USDA might elaborate a prerelease review system with all the features described above as requirements for the permits now issued under the statutes. But that attempt would encounter at least one jurisdictional impediment. Both the plant pests and the noxious weeds are defined as organisms that can directly or indirectly injure plants or certain environmental interests. A narrow reading of the language can injure, in contrast for example, to may injure, would exclude from the statute's jurisdiction organisms whose effect on the environment are unknown. It is likely that as time goes on, organisms will be developed that may injure plants or other environmental interests, but whose actual effects will not be known until after testing is done.

If the statutes do not confer jurisdiction over plant or organisms whose effect have not been demonstrated, they cannot be used to require the needed testing. Thus the jurisdictional requirement appears to undercut the establishment of a broad prerelease review program.

Third and finally is the conflict of purpose. The agricultural statutes are deficient because their underlying purpose is not broad environmental protection but the promotion and the protection of agriculture. Eventually cases are going to arise in which agricultural interests will conflict with broad environmental interests.

It is not clear in such situations the degree to which USDA acting under these statutes would be legally required or perhaps even able to protect the environment.

Senator DURENBERGER. Thank you very much. Mr. Goldhammer.

STATEMENT OF DR. ALAN GOLDHAMMER, DIRECTOR, TECHNICAL AFFAIRS, INDUSTRIAL BIOTECHNOLOGY ASSOCIATION

Dr. GOLDHAMMER. Thank you very much, Mr. Chairman.

My name is Alan Goldhammer and I am director of technical affairs, Industrial Biotechnology Association. I am here today to present the association's views on Federal regulatory efforts directed toward the environmental uses of biotechnology.

We believe that the environmental application of genetically engineered organisms will offer distinct benefits to society. These will come about through improvements in the microbial pesticide area, reducing the reliance on chemical pesticides; improvements in

plant-associated microbial nitrogen fixation, reducing the need for chemical fertilizers; improvements in microbial waste degradation procedures that will offer alternative to the present "burn or bury" approaches to toxic chemical control; and finally, direct genetic manipulation of crop plants that will lower the farmer's cost and thus improve his profit margin.

Because of the rapid transfer of biotechnology to the commercial sector there have been questions as to how products arising from these genetic manipulations would be regulated by Federal agencies.

In order to clarify this, the OSTP issued a coordinated framework for regulation of biotechnology back in December 1984. That statement contained proposed policies from each of the major Federal regulatory agencies regarding administration of their statutes along with a matrix listing applicable Federal statutes.

It is important to note that these statements were proposals designed to elicit comments from the public and not final agency policies. At present the agencies are working on a final policy for regulation based upon those proposals and the public response to them.

In the midst of these deliberations, concern has risen over the handling of two early products, Frostban, a microbe designed to inhibit frost formation on plants, and Omnivac, a vaccine directed against swine pseudorabies.

We would point out that these concerns were procedural in nature and not based on any identifiable hazards. Lost amidst the controversy was the fact that both products are organisms that have genetic material deleted and by definition are not recombinant DNA generated organisms. They are no more different than existing organisms.

In IBA's comments to OSTP regarding last year's proposals for regulatory policy, we argued that the regulatory focus should be product driven as opposed to technology driven. At present the only reasonable way in which to review biotechnology products designed for environmental use is on a case-by-case basis. The composition and use of the final product will define the scope of the risk assessment leading to product approval. Guidelines should be adopted which balance potential benefits against potential risk.

Because there has been concern voiced over the use of genetically engineered organisms in the environment, IBA believes that it is prudent to examine field releases. This view was communicated to the regulatory agencies in our reply last year. Although this necessitates regulatory agencies looking at what has been classified as research and development activities that have been excluded from oversight, the perception of uncertainty surrounding some of these products appears to warrant this Federal regulatory role if sound scientific principles are employed. Agency oversight of such research activities should be reevaluated periodically so that the regulatory burden can be adjusted to reflect actual risks.

In addition to the above, the following points are key to the overall Federal regulatory effort.

Agencies should have clearly defined procedures for both final product review and approval as well as interim field test approval for those cases where necessary. These procedures should include specific timeframes for review.

Procedures designed to evaluate field test protocols for genetically engineered organisms should be consistent whether the protocol is submitted by a researcher from a commercial concern or from the nonprofit university sector.

Review procedures should have a mechanism to protect confidential business information. This is quite important since reviews of field test protocols may occur years before product commercialization.

Reviews should be conducted by that section of the agency that has statutory authority. If additional scientific expertise is required to evaluate a given proposal, the agency should be able to convene a panel of experts to provide advice.

Coordination of the Federal efforts in the risk assessment and regulatory areas are important. Development of appropriate scientific expertise is essential.

IBA recognizes that this process of developing a sound regulatory framework for biotechnology has been complex and time consuming. The agencies have put a good deal of effort in developing policies for regulation and IBA anticipates the forthcoming policy statements.

However, it is of utmost importance that the resulting Federal regulatory role be based on sound scientific principles and be prepared to address those product areas that present uncertainties.

Needless or uncertain regulations stifle innovation and prove harmful to companies competing on world markets.

IBA believes that the regulatory policy encompassing the principles mentioned above can satisfactorily address the public concerns about health and safety issues while maintaining a competitive position for the United States in this world economy.

Senator DURENBERGER. Thank you very much.

Ms. Mellon, have you reviewed the USDA testimony presented here today, and if you have, give us your views briefly on the likelihood of the new structure they are proposing at USDA to solve the problems that you've addressed?

Ms. MELLON. Well, I haven't had a chance to review the statements. I heard the testimony that was given. I haven't had a chance to review any written version of that testimony nor to review the USDA policy statement. It has not yet been released.

Senator DURENBERGER. Well, that's fine.

Ms. MELLON. From what I have heard though—I did not hear today in the testimony any—to me the legal issues were not addressed at all. It reminded me of building a house, a very large house, the framework is going up, but the foundations have not really been checked to see how adequate they are. And I have a fear that once somebody looks at them they are going to find that there are some wide cracks and big holes.

Senator DURENBERGER. All right.

Mr. Goldhammer, were you here for my opening statement and the examination of Mr. Moore? I implied at least in the statement and maybe in the tone of some of the questions that we in the governmental side might be off to a shaky start in our interface with the industry.

Is there, in your opinion, any way in which some of the problems that developed in a couple of the cases that we have talked about,

particularly the two cases, for example, that resulted in fines and so forth? What is your view on how we might have avoided some of those problems that occurred in those cases? Or is there any way to have avoided those problems?

Dr. GOLDHAMMER. I think that the major focus, as I said in my testimony, needs to be on the actual products. And if we have examined these products as to what they are, we can conduct a risk assessment. In fact that the ice-minus bacterium, as Dr. Moore pointed out, does occur in nature naturally, and here is a company that has just taken another approach to generating the same type of organism. Now, does this present any intrinsic hazard of its own?

I think the scientists have argued long and hard on this that, no, it doesn't for that particular product.

Similarly for the swine herpes vaccine. This product was analogous to three products that are already licensed under the Virus-Serum-Toxin Act by USDA. And does using genetic engineering to snip out these genes present any incremental hazard versus the already existing licensed vaccines?

Again, the scientists have argued, no, in fact it does not. In fact, it provides for a safer vaccine because it doesn't have the possibility of reverting in the animals causing possible pathogenic effects as do existing vaccines.

I think that if we did focus on the products that genetic engineering was using we could then really examine them and say, has there been any real hazards and the public put at risk from these particular products? We believe the answer is no for that.

Senator DURENBERGER. Senator Baucus.

Senator BAUCUS. Thank you, Mr. Chairman.

Mr. Goldhammer, Ms. Mellon suggested three problems. One is inadequate coverage of present agricultural statutes. She says taken together they do not give USDA authority to regulate all engineered organisms.

Second, she says there is lack of authority to conduct prerelease review.

Third, she suggests that there's conflict of purpose in statutes between environmental protection on the one hand and promotion and protection of agriculture, at least under USDA's statutes on the other.

I am just curious as to what your response would be to her three points.

Dr. GOLDHAMMER. These are all concerns that have been brought up to us. In fact, within the association and our member companies, we have come to similar conclusions. That is why we are anxiously awaiting publication of their latest regulatory statement to see if these are in fact addressed.

As I pointed out, we do agree that prerelease review of products, at least at present, is perhaps a necessary fact of life for the industry and we want to see this encompassed within the regulatory framework. We don't want to end up in the courts at all if we can avoid it.

Senator BAUCUS. You'd like to see some statutory authority for prerelease testing?

Dr. GOLDHAMMER. This is something that we acknowledge needs to be encompassed within the regulatory framework.

Senator BAUCUS. What about the potential conflict of purpose?

Dr. GOLDHAMMER. This is a problem I think that agencies can get themselves into because if they do have a promotional aspect within the agency. That conflict needs to be resisted.

I would point out that the same thing exists in Health and Human Services where you've got a regulatory agency, the Food and Drug Administration, as well as an agency that promotes a science, the National Institutes of Health, and those two functions have been kept distinct within that agency. My understanding is that the USDA intends to do the same thing.

Senator BAUCUS. You understand that the USDA intends to do the same thing?

Dr. GOLDHAMMER. Yes.

Senator BAUCUS. Separate?

Dr. GOLDHAMMER. Yes.

Senator BAUCUS. Would you be satisfied with that separation?

Dr. GOLDHAMMER. We hope that that can be accomplished.

Senator BAUCUS. Ms. Mellon, would you be satisfied with that intended separation? Do you think it will work?

Ms. MELLON. My view right now is I don't think it will work.

Senator BAUCUS. Why would that be?

Ms. MELLON. Well, referring to the HHS example. There is statutory authority for each of the two subsections of the agency that are undertaking the two separate tasks. Each has guidance from Congress on how it is supposed to carry out its task.

Here we have an agency that is under legislation that really only addresses one of the two functions that we are asking it to undertake. It's under legislation that explicitly authorizes it to go out there to protect and promote agriculture. There is no compensating legislation under which an environmental protection function could develop or to which it could turn for guidance on environmental matters. Exactly how is it USDA to know what it's supposed to do as it undertakes this new function of protecting the environment.

Now, I think as a general solution the notion of separating out something within Agriculture, some organization subcomponent of Agriculture to address this problem is one that should not be rejected out of hand. I think it's necessary. It might even work. But it would have to have a degree of separation that I don't think is even approached in the testimony we heard this morning describing different lines of review.

Senator BAUCUS. Dr. Goldhammer, could you please tell us from the industry's point of view how difficult it is to get insurance? And second, if it is difficult, why it is difficult. And third, what can be done to help provide adequate insurance coverage?

Dr. GOLDHAMMER. The insurance problem as the Senator probably well knows is not unique to biotechnology. You know, we have seen municipalities and day-care centers having great difficulty getting liability insurance.

We are in the process right now internally of trying to assess whether this is a major problem for the biotechnology companies themselves. We do have members that are large and diversified chemical and pharmaceutical companies who do have liability in-

surance and can cover their existing testing programs under those policies.

The interesting thing in our survey of the Federal statutes, we were unable to find any product-oriented regulatory statute that requires liability insurance as a prerequisite for product approval. And would question, you know, why is it all of a sudden that this is being asked of the biotechnology industry? Particularly in the absence of any defined hazards from its products.

Senator BAUCUS. So you feel that should not be a requirement?

Dr. GOLDHAMMER. We certainly do not unless there is going to be a massive revamping of Federal statutes making it required for every product——

Senator BAUCUS. Apart from the requirement, is the industry concerned about the difficulty of securing liability coverage?

Dr. GOLDHAMMER. We are going to be having a meeting in the middle of June, to assess this. We have not yet done a survey of our member companies.

Senator BAUCUS. So you are telling me you don't know if it's a problem?

Dr. GOLDHAMMER. Yes; that's a fair summation, yes.

Senator BAUCUS. OK. So my earlier understanding is not quite accurate. It has been my understanding that it has been a significant problem for the industry.

Dr. GOLDHAMMER. Well, I would imagine there probably are some companies that are having a difficulty and are going the self-insurance route. But then on the other hand, we have a number of major industrial Fortune 500 companies that go that same route because they feel that it is better to self insure themselves than go through an independent insurance carrier.

Senator BAUCUS. What about the smaller outfits that can't self insure as easily? We want to encourage a little entrepreneurship here, don't we?

Dr. GOLDHAMMER. Sure, sure. But I guess the question that would come up is are they doing anything that is scientifically hazardous. It gets back to the question you raised a little earlier, that we really don't know if in fact these are just perceived risks or they are real risks.

So you return to insurance underwriters. Are they capable of understanding the technology in making a fair judgment about the risks that they're insuring In essence, throwing the ball back in their court. I am not sure. I haven't followed the insurance industry. We did a survey for one of the underwriting groups 3 years ago and I remember the results that came back to us, that they said that there were no unique hazards associated with this technology.

Senator BAUCUS. When will your survey be complete?

Dr. GOLDHAMMER. I think the meeting is supposed to take place the second week in June.

Senator BAUCUS. So the results of that study will be available when?

Dr. GOLDHAMMER. Well, I would imagine shortly thereafter. I don't know. I am not the one that is coordinating that, so I can't give you a firm answer.

Senator BAUCUS. OK. Thank you.

Thank you, Mr. Chairman.

Senator DURENBERGER. Thank you very much for your testimony. I thank everyone for their contributions; the hearing is adjourned.

[Whereupon, at 12:20 p.m. the subcommittee adjourned.]

[Statements submitted for the record and responses to additional questions follow:]

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TESTIMONY OF THE

HONORABLE HAROLD VOLKMER (D-MO)

BEFORE THE

TOXIC SUBSTANCES AND ENVIRONMENTAL OVERSIGHT SUBCOMMITTEE

OF THE

SENATE ENVIRONMENT AND PUBLIC WORKS COMMITTEE

May 16, 1986

Mr. Chairman and Members of the Toxic Substances and Environmental Oversight Subcommittee of the Senate Environment and Public Works Committee, I appreciate the opportunity to testify today about the Federal Government's role in the regulation of biotechnology. I believe that biotechnology holds great promise for this nation and the world. The potential of genetic engineering to enhance our lives has led companies in this country and abroad to spend millions of dollars to develop and market a wide variety of products that only a decade ago were beyond our dreams.

However, the ability to alter the genetic make-up of living things presents undeniable risks. While chemicals and even radioactive products can be isolated and contained, genetically engineered organisms are alive and procreate. These organisms, once released into the environment, have the capacity to spread and dominate, with as yet unknown consequences. They cannot be recalled.

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A staff report prepared for the Subcommittee on Investigations and Oversight in February 1984, during the Chairmanship of the Honorable Albert Gore, Jr., concluded that release of genetically engineered organisms into the environment posed a "low probability of high consequence risks" and that the then current federal regulatory framework did not guarantee that "adequate consideration will be given to potential environmental effects of a deliberate release."

Obviously, we cannot afford to rely on hindsight to determine whether biotechnology products released into the environment have dangerous side effects associated with their beneficial use. If we in Congress are to build and maintain the public confidence necessary for the acceptance and success of biotechnology in this country, we must see to it that there is in place a clear and effective system to determine whether particular genetically engineered organisms are safe before they are released in nature.

The first level of federal review of biotechnology was established by the guidelines of the National Institutes of Health (NIH) Recombinant DNA Advisory Committee (RAC). These guidelines pertained to laboratory practices in experiments involving recombinant DNA technology. Voluntary compliance with the guidelines was widespread and is no doubt responsible for the pristine record of safety associated with genetic engineering laboratory research.

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The next substantial government action regarding biotechnology came about in December 1984 when various federal agencies published in the Federal Register a coordinated framework for the federal regulation of biotechnology. Each agency involved with the regulation of biotechnology products described how products developed through recombinant DNA technology would be reviewed under existing statutes and regulations.

The December 1984 policy statements by the agencies were interim guidelines which were to be followed by more elaborate, coordinated policy statements and rules that would be the result of extensive study by and cooperation among the agencies. These long-promised permanent guidelines are being prepared under the guidance of the Biotechnology Science Coordinating Committee (BSCC) which has been established by the White House under the Office of Science and Technology Policy (OSTP).

The Federal Government's interim guidelines were put in place in the nick of time; for by December of 1984 several companies were already proposing to conduct field trials of genetically engineered organisms. As early as 1983, one company, AGRACETUS, applied to the NIH RAC for approval to field test a genetically engineered tobacco plant. A court decision in a law suit brought by Jeremy Rifkin delayed field testing of the plant by requiring NIH to perform an environmental assessment of the impact of the proposed field test. AGRACETUS then applied to USDA for permission to field test the plant. USDA, however, stated only

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that the plant was not a "plant pest" (according to the Federal Plant Pest Act) and therefore the field test "posed no problem."

This non-decision by USDA prompted AGRACETUS to return to the NIH RAC which approved the field test of the plant in 1985. AGRACETUS has not yet conducted the field test.

Another company, CALGENE, applied directly to USDA for approval to field test a different type of genetically engineered tobacco plant. That application although similar to AGRACETUS', was reviewed by the Agricultural Recombinant DNA Research Committee of USDA (ARRC) rather than the Animal Plant Health Inspection Service (APHIS) which had reviewed AGRACETUS' application. No action has yet been taken on CALGENE's application.

The lightening rod that drew public attention to biotechnology was EPA's approval in November, 1985 of a field test by ADVANCED GENETIC SCIENCES ,Inc. (AGS) of a genetically engineered bacteria to prevent frost formation on strawberry plants. This action by EPA and the confused state of affairs at USDA, as seen by the regulatory limbo of the AGRACETUS and CALGENE applications, prompted the first of what proved to be a series of hearings by the Subcommittee on Investigations and Oversight.

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The first hearing was held on December 4, 1985--one year after publication of the interim guidelines and less than one month after approval of the "ice minus" experiment by AGS. The purpose of the hearing was to examine the federal government's preparedness to regulate and review the products of biotechnology. Specifically, the Subcommittee wanted to examine the process EPA followed in approving the AGS field test, and wanted to learn how USDA intended to resolve the regulatory confusion that had surfaced within USDA.

USDA's regulatory posture under the interim guidelines received additional attention at this hearing following the release of a GAO report commissioned by the Hon. Don Fuqua, Chairman of the House Science and Technology Committee. That report revealed that USDA was funding 87 projects nationwide that could lead to the deliberate release of genetically engineered organisms, the majority of the releases to occur within the next five years. Only three of the projects involved formal programs of risk assessment.

At the hearing, industry representatives testified that delay and confusion among and within the agencies was handicapping U.S. companies in the international race to develop and market biotechnology products. EPA and USDA officials admitted that there had been initial uncertainty in implementing the interim guidelines. However, EPA cited its scientific review of the AGS proposal as an example of how EPA would examine future field test

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proposals. EPA felt that, in the AGS review, it had adequately ensured that the environment was protected while not unduly delaying the field testing necessary to develop and market a new biotechnology product.

USDA representatives discussed how USDA proposed to coordinate review of biotechnology products among the various divisions at the Agency. Proposals for research and field testing would go first to the ARRC, which would then refer the proposal to the appropriate division of APHIS. Because the ARRC is composed of representatives from both USDA's Science and Education division and the Market and Inspection division, USDA believed that the previously confusing and overlapping jurisdiction of those two divisions would be resolved.

Altogether, the testimony at the hearing presented a picture of regulatory certainty and thoroughness. Even more encouraging was the assertion by the agencies and by OSTP, that the new regulatory guidelines would be published in the Federal Register by January 31, 1986.

Unfortunately this picture evaporated within a few short months. In February, 1986, the Subcommittee learned that AGS had conducted unauthorized tests with the the ice-minus bacteria on trees located on the open rooftop of its office building in Oakland, Calif. In addition, these tests, which were intended to determine if the bacteria was pathogenic to fruit trees, were not

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performed under controlled conditions as stated in the company's application to EPA, thereby making the data from the tests suspect.

The Subcommittee convened a hearing on March 4, 1986 to investigate these allegations. The company asserted that a tree was a "contained facility" and therefore EPA authority was not needed for the test. EPA vigorously denied this. As for the use of data obtained from invalid experiments, a member of EPA's Science Advisory Panel that reviewed and approved the AGS proposal testified at the hearing that he could not have approved the field test had he known that the pathogenicity data had been obtained under uncontrolled conditions.

The hearing brought out another troubling fact. The supposedly "remote" test site for the field test was in fact the back yard of an AGS official who lived in a residential neighborhood. EPA , it seems, had never visited the site to confirm its remoteness. In fact, neither EPA nor AGS had discussed the proposed test site with the Board of Supervisors of Monterey County, California where the site was located. As a result, the County invoked its zoning power to block the testing within the county. (EPA has since initiated administrative action against AGS and fined the company the maximum permitted under FIFRA.)

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EPA's lax oversight of the details of the AGS test, the unauthorized release of the bacteria on the company's roof and the company's reporting of scientifically invalid data completely undermined EPA's testimony from the December hearing that the interim guideleines were being effectively implemented. The confusion surrounding the definition of crucial terms such as "contained facility", "release" and "remote" demonstrated that the Federal Government had not done a thorough job in communicating its safety concerns to industry.

A month after the AGS hearing, the Subcommittee learned that USDA had licensed a genetically engineered live virus veterinary vaccine without review of the vaccine by the ARRC, supposedly the focal point of USDA's biotechnology review program. The Subcommittee's investigation revealed several disturbing facts.

First, the inventor of the vaccine, Dr. Saul Kit of the Baylor College of Medicine, had participated in a field test of the vaccine on 1400 pigs in Texas without notifying, or receiving the approval of, the Institutional Biosafety Committees (IBC) at the Baylor College of Medicine and at Texas A&M, as required by the NIH RAC guidelines. Second, USDA did not classify the vaccine as a "recombinant organism" until after the license applicant, TECHAMERICA GROUP, Inc., had field tested the vaccine in several midwestern states. Third, after USDA classified the vaccine as a "recombinant organism", it did not submit the proposal to license the vaccine to the ARRC for review. This

omission directly contradicted the testimony USDA provided at the December hearing regarding review procedures within USDA. Finally, USDA did not publish an environmental assessment of the effects of releasing the genetically engineered vaccine before it licensed the vaccine, as required by the National Environmental Policy Act. NEPA as interpreted in the decision in Foundation on Economic Trends v. Heckler,756F.2d.143 (D.C. 1985).

The facts surrounding licensing of the vaccine demonstrated once again the confusion regarding definition. Dr. Kit maintained at the hearing that the vaccine was not a "recombinant organism" and that innoculation of a pig with the vaccine was not a "release". However Dr. Kit may defend his opinion (which is not shared by the Baylor IBC, the Texas A&M IBC or NIH officials), the fact remains that Dr. Kit, like AGS, chose not to consult with the appropriate federal and local officials for approval of what was unarguably a test outside of a laboratory of a product developed through recombinant DNA technology. (NIH, Baylor and Texas A and M have instigated investigations of Dr. Kit's possible violation of the NIH guidelines.)

This "pioneer" behavior regarding the release of biotechnology products undermines the public confidence in biotechnology that had been created by industry's voluntary compliance with the NIH RAC guidelines governing laboratory research.

The new federal guidelines promised for January 31, 1986 are now long overdue. Proposals to field test genetically engineered organisms, however, have not stopped. Monsanto has applied to EPA for approval to test a genetically engineered microbial pesticide. EPA's Science Advisory Panel recommended to EPA that the test go forward. EPA is expected by most observers to grant Monsanto a permit to conduct the test on a test plot located in my district in Missouri. The county has now notified Monsanto that the test violates the county zoning code. Who can say that this action by the county is not a direct result of the public's lack of confidence in biotechnology stemming from the incidents I have described today?

The Congress has not merely waited for the new federal agency guidelines with bated breath. Congressman Fuqua has introduced a bill entitled the Biotechnology Science Coordination Act of 1986 (H.R.4452) to create a clear and certain pathway for biotechnology products to travel from the lab to the market. The Act creates a three-tiered permit system at both EPA and USDA that accents scientific review and data gathering at different levels of use and distribution. It also creates a joint government-industry research program to investigate some basic questions related to the effect of releasing genetically engineered organisms into the environment.

11

In the Senate, Senator Durenberger has introduced the Biosafety Act of 1985 (S.1967) that amends the Toxic Substances Control Act to give EPA the authority to regulate genetically engineered micro-organisms. The bill requires a permit for experimental use, distribution in commerce, or use in manufacturing of these organisms.

The new federal guidelines are now promised for the end of May. The Subcommittee on Investigations and Oversight intends to hold a hearing on May 22 to examine the new guidelines. If the guidelines are not published by then, the hearing will focus on the cause of the delay that is hampering industry and government action.

CALGENE has temporarily suspended its application to USDA to field test a genetically engineered tobacco plant. This resulted from the continuing regulatory confusion at USDA. Both the AGS and MONSANTO field test have been delayed by or met with local opposition. Obviously, the federal government and the biotechnology industry must act soon to restore public confidence in this new science and to install a reliable, thorough system of federal review of planned releases of genetically engineered organisms.

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The history of federal involvement in the regulation of biotechnology is an inconsistent one. No one disputes the great value of the NIH RAC guidelines for biotechnology research. Those guidelines relied on cooperation more than coercion, caution rather than prohibition. Unfortunately it is easier to enforce guidelines in a laboratory than in a field. When genetically engineered organisms are released into the open, the environment itself becomes the laboratory. Therefore voluntary guidelines and blind faith won't do. Yet, federal review of deliberate releases has been either too little - as in the AGS case; too late - as in the vaccine case; or not at all - as with the Calgene application lying dormant within USDA for so long and now temporarily suspended.

The Federal Government must fill its role in biotechnology and fill it soon. That role requires the government to conduct the best scientific review possible of genetically engineered organisms proposed for release into the environment to ensure that each organism holds the key to a treasure - not Pandora's Box. We have already asked future generations to clean-up our toxic chemicals and nuclear waste. Let's not add genetically engineered organisms gone astray to the list.

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

FOR RELEASE ON
THURSDAY, MAY 8, 1986

STATEMENT FOR THE RECORD BY
BRIAN P. CROWLEY
RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION

FOR THE
SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL QUALITY
OF THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

ON THE
GENERAL ACCOUNTING OFFICE'S
REVIEWS OF THE DEPARTMENT OF AGRICULTURE'S
BIOTECHNOLOGY RESEARCH EFFORTS AND
REGULATORY PROGRAMS AND ACTIVITIES

Mr. Chairman and Members of the Subcommittee:

At your request, we are providing this statement to assist you in deliberating the preparedness of the federal government to oversee and regulate biotechnology. The statement highlights two of our recently issued reports having to do with the U.S. Department of Agriculture's (USDA's) biotechnology research efforts and its regulatory programs and activities. These reports resulted from work done at the request of Chairman Don Fuqua, House Commmittee on Science and Technology.

The first report, The U.S. Department of Agriculture's Biotechnology Research Efforts (GAO/RCED-86-39BR, Oct. 25,1985), provided a previously unavailable inventory of biotechnology

research projects conducted or sponsored by USDA in fiscal years 1984 or 1985. Some 778 research projects were identified at an annual cost to USDA of $40.5 million. Of these projects, 87 were expected by the researchers to involve the deliberate release of genetically engineered organisms into the environment within 1 to 5 or more years. The 87 projects were being conducted in 28 states. Such releases are to be done for the purpose of further testing rather than for the purpose of achieving widespread applications.

In conjunction with the above, Chairman Fuqua also asked us to review USDA programs and activities that relate to biotechnology and how such efforts relate to decisonmaking concerning the deliberate release of genetically engineered organisms into the environment. This work is the subject of our recently issued report entitled Biotechnology: Agriculture's Regulatory System Needs Clarification (GAO/RCED-86-59, March 25, 1986). It is from this latter report that we have drawn the remainder of the remarks that are presented to you in this statement.

BACKGROUND/RESULTS IN BRIEF

Little or no evidence exists that harmful, genetically engineered organisms have been created, but few experts believe that the new biotechnologies (particularly the technique of prime interest and concern known as "recombinant DNA") are without risk. This potential risk and biotechnology's broad application have led several federal agencies, including USDA, to regulate the research and commercialization of biotechnology.

USDA helped formulate early policy decisions concerning recombinant DNA research and has helped develop the new biotechnologies. Its future involvement is likewise expected (1) to be significant because much of the research in biotechnology is agriculturally oriented and (2) to intensify because regulatory responsibilities of the National Institutes

of Health-Recombinant DNA Advisory Committee--the federal government's primary overseer of biotechnology until recently--are now shifting to various federal agencies, including USDA. Although this is the case, USDA had not--as of November 1985--formulated a biotechnology regulatory structure (particularly with regard to deliberate releases of genetically engineered organisms into the environment) or provided its Agriculture Recombinant DNA Research Committee with the authority and direction it needed to effectively act as the Department's focal point for biotechnology matters. In addition, USDA had done little to communicate to the Congress and the public both the benefits and risks of biotechnology as well as its plans to minimize those risks.

USDA PHILOSOPHY TOWARDS REGULATING BIOTECHNOLOGY

USDA has stated often that it is capable of regulating and minimizing the associated risks of the new biotechnologies because of its (1) many years of research and accumulation of extensive knowledge and (2) cautious approach to the containment, testing, and deliberate release of organisms into the environment. In addition, it has stated that products developed from the new biotechnologies will be similar to conventional products and can be similarly regulated.

USDA'S REGULATORY STRUCTURE NEEDS CLEARER DEFINITION

USDA has few programs or activities that relate exclusively to biotechnology; rather, its oversight in this area has been handled by agencies within the Department that were established before the new biotechnologies and that have other regulatory and/or research responsibilities. In addition, the Agriculture Recombinant DNA Research Committee was established in 1976 to oversee and coordinate matters relating to recombinant DNA research. Despite such mechanisms and certain recent initiatives to overcome regulatory uncertainty, we concluded

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that USDA needed a clearer definition of its regulatory structure, particularly with regard to approving requests to deliberately release genetically engineered organisms into the environment. For instance, the first two such requests submitted to USDA for approval were handled by two different groups within USDA, although the requests were essentially identical. In general, agencies within USDA were struggling for regulatory control, questions remained as to which agency was responsible for what, and the Agriculture Recombinant DNA Research Committee--USDA's designated focal point for biotechnology--lacked authority and direction.

USDA has been hesitant in developing a well-defined regulatory structure because (1) it did not want to impose cumbersome regulations that might stifle growth in biotechnology, (2) the timing and pace of its actions have been influenced by the White House's Office of Science and Technology Policy, which has been examining biotechnology regulation and coordinating the actions of many federal agencies, and (3) several lawsuits filed by opponents of biotechnology have created some anxiety.

Recently, USDA has set more firmly in place a general framework under which it will regulate biotechnology. Still needed at the time of our review, however, were procedural details and specificities expected in a regulatory structure--procedures that minimize questions regarding who is responsible for what but that are are flexible enough to encompass an expected wide range of biotechnology research and product development. USDA also needed to more clearly establish the authority and duties of the Agriculture Recombinant DNA Research Committee, thus giving it the power to effectively act as USDA's focal point for biotechnology.

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REDUCING CONCERNS THROUGH IMPROVED COMMUNICATION

The need for USDA to inform the Congress and the public about the benefits and potential risks of biotechnology is expected to intensify as many experiments in biotechnology move toward environmental release. Such communication would (1) lessen the fears aroused by experiments involving deliberate releases of genetically engineered organisms and (2) result in more informed discussions about the speed and/or restrictions under which biotechnology is allowed to proceed.

RECOMMENDATIONS

We recommended in our most recent report that USDA:

--Complete the development of a formalized, well-defined regulatory structure over biotechnology, particularly with regard to deliberate releases of genetically engineered organisms into the environment. We believe such a structure should be sufficiently detailed to minimize questions about who in USDA is responsible for decisions in particular areas and flexible enough to encompass the wide range of biotechnological research and product development expected. It should clearly identify the regulatory procedures for handling requests to license biotechnology products and approve the deliberate release of genetically engineered organisms into the environment. These procedures should help ensure the consistent handling and treatment of such requests.

--Provide the Agriculture Recombinant DNA Research Committee (or any successor to this committee) with the authority, prestige, and sense of direction it needs to effectively act as USDA's focal point for biotechnology. The committee should have the power to resolve

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differences that may arise with regard to biotechnology within USDA (e.g., between the regulators and researchers) and to act on USDA's behalf in resolving differences between USDA and other federal agencies, such as the National Institutes of Health, Environmental Protection Agency, and Food and Drug Administration.

--Look for and take advantage of opportunities to improve and increase the communication of its views on biotechnology, both in terms of the benefits to be derived and the risks that must be considered and managed. The purpose of such communication should be to foster a more open, frank, and informed discussion about USDA's views on biotechnology.

In commenting on this report, USDA raised a number of points related to the report's contents. However, USDA's comments did not specifically address our recommendations.

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In closing, we believe that the time has come for USDA to have its biotechnology regulatory structure in place. It has already dealt with the licensing of a number of genetically engineered veterinary biologicals, and it has begun to receive requests for approval to release genetically engineered organisms into the environment for further testing purposes. USDA's workload can only be expected to intensify as many more small-scale, contained experiments conducted thus far in research laboratories progress to the point where further testing in the environment is desired, or, where companies with substantial investments in biotechnology research begin to push towards the licensing and commercialization of the products that have thus been produced. USDA can facilitate these processes, thus generating the benefits of biotechnology and at the same time safeguarding the public and the environment from risk, only

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if its regulatory structure is in place, sufficiently defined, and made known to all who must comply with or are otherwise interested in it.

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STATEMENT OF
JOHN A. MOORE
ASSISTANT ADMINISTRATOR FOR PESTICIDES
AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON TOXIC SUBSTANCES
AND ENVIRONMENTAL OVERSIGHT
OF THE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

May 16, 1986

Good morning, Mr. Chairman and members of the Subcommittee. I welcome the opportunity to appear before this Subcommittee to discuss the Office of Pesticide Program's regulatory activities related to biotechnology. The hearing today is particularly timely, since we have just announced our decision to approve the field testing of biotechnology products by Dr. Steven E. Lindow of the University of California.

I would like to begin my testimony by describing our authority to regulate in this area and then discuss our evaluation of applications for experimental use permits and the investigation of Advanced Genetic Sciences (AGS).

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Overall Scope and Authority

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is a risk/benefit balancing statute. Before allowing the use of a pesticide, EPA is required to make a judgment that the pesticide will perform its intended function without causing unreasonable adverse effects on people or the environment. The statutory definition of a pesticide is any substance intended for preventing, destroying, repelling, or mitigating any pest. EPA has determined that any product that is intended to protect agricultural crops from frost damage by mitigating or inhibiting the growth of natural frost promoting bacteria, is a pesticide.

Before a pesticide can be distributed or sold in commerce, it must be registered with EPA. This requirement applies to all chemical and microbial pesticides, including those that are genetically engineered, unless they are specifically exempt by regulation. All pesticide registrations must be supported by adequate data. The FIFRA and implementing Agency regulations give the Agency sufficient latitude to obtain whatever data are needed to assess risks. In the case of genetically engineered microbial pesticides, we have thus far taken a case-by-case approach to determine data requirements. This means that we have required the generation of additional data depending upon the specific microorganism, the engineering method and the proposed use pattern.

Under FIFRA Section 5, EPA is authorized to grant an experimental use permit (EUP) for a limited use of an unregistered pesticide. Our regulations require EUPs for all tests on greater than 10 acres of land or one surface acre of water. At the time we issued this regulation - in 1975 - it was generally presumed that an EUP was not required for smaller testing, that the potential risks from such tests did not warrant EPA oversight. All that has changed. This presumption may not be appropriate for certain microbial pesticides. We therefore issued an Interim Policy in order to clarify that EPA does believe that even small scale testing of genetically engineered non-indigenous microbial pesticides warrants our oversight. We have established a two-step process for evaluating proposed experiments with these microbes: first, a notification and then, if necessary, an experimental use permit application.

Interim Policy on Small Scale Field Policy

On October 17, 1984, we issued an interim policy on small scale field testing of certain microbial pesticides. Our purpose was to implement a mechanism for evaluating and addressing concerns about the potential risks raised by even small scale use of genetically engineered and non-indigenous microbial pesticides. For example, we are concerned about these pesticides' potential to survive and to replicate or

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transfer genetic material in the environment. We are also concerned about their ability to spread from the test site and the possible lack of natural control mechanisms for the new organisms. I would like to emphasize that we are interested primarily in direct environmental release - not studies conducted in a controlled laboratory, growth chamber, or other contained facility.

Our interim policy of October 1984 requires that we be notified at least 90 days prior to the proposed testing, and we have specified that the following minimum information and data should be contained in the notification:

- o detailed information on the test and the microbe to be tested, including:
  - identity
  - natural habitat
  - host range
  - growth and survival
  - effects on non-target organisms
- o In addition, for genetically engineered microbes, information on:
  - method of construction
  - potential for genetic transfer
  - competitiveness

After EPA has received the notification, the Agency has 90 days to review it and determine whether an EUP is required. If the notification responds to our questions and no significant risks or need for oversight is foreseen, then an EUP is not

necessary and the test may proceed. However, if questions remain and the Agency needs additional data to answer those questions or if we want to ensure closer EPA oversight, then we may require an EUP.

Thus far, most of our efforts in the area of biotechnology have focused on reviewing notifications under the interim policy and evaluating EUP applications.

The Agency is aware that its regulatory activities have the potential to inhibit the development of a potentially profitable and socially beneficial technology. I believe that our regulatory process balances the social need to evaluate the risks of this technology against the potential benefits. This is consistent with the legislative mandate to manage pesticides on a risk/benefit basis.

Applicability of Interim Policy to AGS Test

I would now like to address our interim policy and how the process I've just outlined applied to the testing proposed by Advanced Genetic Sciences (AGS).

The AGS product -- a non-ice nucleating bacteria (INA^-) with the trade name Frostban -- and proposed experiment are subject to the interim policy because INA^- bacteria are genetically engineered pesticides and the proposed experiment involves their direct release into the environment. The AGS product is considered a pesticide because the INA^- bacteria

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mitigate the effects of the natural frost promoting bacteria, which are considered pests because of their deleterious effect on economically important plants. AGS did submit a notification to EPA in October 1984; the Agency evaluated the notification and our scientific assessment was reviewed by an independent panel of experts -- a subpanel of the FIFRA Scientific Advisory Panel (SAP). I would like to note that the members of the SAP subpanel were selected because of their expertise in such areas as plant pathology, meteorology, and microbiology. The experiment appeared to pose a very low likelihood of risk, but the Agency and the subpanel concluded that this needed to be substantiated with additional scientific data and further documentation of existing data.

AGS was informed that an EUP was required; the applications were submitted to EPA on June 27, 1985. This began a review process similar to that for the original notification, including review by the scientists within the Office of Pesticide Programs and the development of a risk assessment; the scientific review of the application and the risk assessment within the Agency, by other agencies (USDA, NIH, FDA) and by the SAP subpanel.

Virtually all of the information relating to the Agency's review of the AGS proposed test is available to the public, including the assessments of our own scientists and

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the comments of the SAP subpanel. We announced receipt of the EUP applications, summarized the proposal and made available to the public the non-confidential portion of the applications. This notice also solicited public comments on AGS' proposed test. EPA received two public comments, only one of which raised substantive concerns. The concerns were carefully reviewed by EPA and by independent scientists. Our response to the comments was also made public. As you can see, the review process which we established for the AGS application -- as well as that of Dr. Lindow -- is one which is open; our decisions can be scrutinized by the public and the entire scientific community.

I would like to turn now toward the substantive aspects of our scientific assessment of the AGS product. The most critical issues were:

- plant pathogenicity;
- potential effects on survival and geographic range of plants and insects;
- potential effects on rainfall patterns.

Our assessment of these issues was intensive and comprehensive. By way of example, I will elaborate on how we reached a decision concerning the potential effects on rainfall patterns. Because this concern was raised by an earlier NIH review, we invited a meteorologist to sit on the SAP subpanel. The potential effects of the AGS test on precipitation were discussed at the SAP subpanel meeting on the AGS notification.

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Subsequently, EPA also contacted the experts cited in the public comments and again consulted SAP subpanel members. All of the atmospheric scientists consulted by EPA agreed that there was no firm evidence that the naturally occurring INA^+ bacteria play a role in precipitation formation. Further, they concluded that there was virtually no likelihood that displacement of INA^+ by INA^- bacteria on plants in a small scale test plot would affect precipitation patterns.

After considering this and other issues I already mentioned, EPA came to the conclusion that the proposed experiment posed no foreseeable risk to human health or the environment. On November 14, 1985, EPA granted AGS two EUPs (one EUP for Pseudomonas syringae and the other for Pseudomonas fluorescens).

Test Site Location

The risk assessment which resulted in our approval of the AGS EUPs did not focus on specific site details. EPA believes that the conclusion of "no foreseeable risk" is valid, irrespective of the specific site. Yet the EUPs we issued required AGS to notify EPA 15 days before the initiation of the experiment and required that an authorized representative of EPA be present when the experiment is conducted. In addition, we determined that during the experiment air monitoring would be undertaken jointly by EPA and AGS, necessitating a site visit by EPA before the test.

On December 12, 1985, EPA personnel visited the test site and determined that AGS would have to gain access to adjacent properties in order to conduct the monitoring specified in the EUPs. We then amended the terms of the EUPs on January 3, 1986, establishing the conditions for dealing with the contiguous land owners. EPA also testified before the Monterey County Board of Supervisors concerning our evaluation of the test site.

Investigation of AGS

On February 24, 1986, EPA was first informed of possible violations concerning some of the pathogenicity tests performed by AGS. Because of the possibility of direct environmental release, on February 27, 1986, we opened a full investigation which focused on an audit of AGS records and facilities to assure the credibility of all the data submitted in the AGS EUP applications. We also reviewed the situation to determine whether any violation of Federal law had occurred.

Our investigation confirmed that there was indeed an environmental release of the genetically engineered bacteria. We also confirmed that parts of the AGS EUP applications did not accurately reflect how certain studies had been conducted.

On March 24, 1986, we announced that EPA had issued an administrative civil complaint against AGS, seeking a fine of $20,000 in penalties. In addition, because of various uncertainties about the roof-top tree pathogenicity tests,

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we have suspended the EUPs until AGS conducts new pathogenicity tests and we have reviewed and approved them. We also informed AGS that if a new test site is selected, it must first be inspected and approved by EPA.

I would like to emphasize that our investigation disclosed no other problems with data submitted by AGS, other than the tree tests. Most important, we have found no evidence that AGS's proposed EUP field tests would result in any significant foreseeable health or environmental risk.

By this enforcement action, I believe that EPA has made it very clear that we will not tolerate any infraction of our regulations for biotechnology. AGS' actions, however, have also made it clear that the establishment of rules by EPA is only one part of the equation. In order for society to benefit from this technology and to feel secure that its potential risks have been evaluated, industry must comply with those rules. We believe our actions in this case have sent a clear message that we insist upon such compliance.

APPROVAL OF LINDOW EUP

On May 13, 1986, the Agency issued two EUPs to Dr. Steven Lindow of the University of California - Berkeley to conduct small scale field tests using two strains of genetically altered bacteria. The purpose of this experiment is to evaluate the potential of Dr. Lindow's INA$^-$ products to control frost damage to plants under actual field conditions. Dr. Lindow will compare their effectiveness with natural non-INA bacteria and a chemical biocide.

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The INA⁻ bacteria producted by Dr. Lindow will be applied to potato seed pieces at planting and will be sprayed on the potato plants soon after they emerge. The first planting will be in May with a second planting in August. This regime will be followed each year for three years. The experiment will utilize two tests plots near Tulelake, California.

As with the AGS applications, the proposed Lindow experiments were scrutinized by Agency scientists, as well as scientists in other agencies and by a special subpanel of the SAP, all of whom recommended approval of the EUPs. In addition, the Agency visited the test sites and laboratory facilities, inspected the books and records of Dr. Lindow's supporting documentation, and participated in a public hearing at Tulelake. State and local agencies and the community surrounding the sites have been notified, and public comments solicited.

Based on our evaluation, the Agency concluded that the small scale field tests proposed by Dr. Lindow are unlikely to pose a significant risk to human health and the environment. I am confident that our approval of these experiments have met the risk/benefit balancing criterion of FIFRA, in that the potential benefits to society from these experiments far outweigh any forseeable risks.

This concludes my prepared statement. I would be happy to answer any questions you may have.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Ronald B. Outen, Ph.D.
Professional Staff Member
United States Senate
Committee on Environment
and Public Works
Washington, D.C. 20510

Dear Ron:

Thank you for the opportunity to elaborate upon my testimony of May 16. The following are our responses to the questions you transmitted in your letter of June 25, 1986.

Question: In the event that the organism released by Monsanto Corporation turns out to have adverse effects will the emergency measures to be taken eradicate the organism?

Response: The chemical treatment portion of the contingency plans described in the response to the second question are designed to kill most (if not all) of the microorganisms in the test plot. In the event that some of the engineered organisms do survive chemical treatment, the plans call for addition of large numbers of naturally occurring microorganisms contained in soil taken from another location on the test farm. This inoculum, containing approximately 10^9 cells per gram of soil, should suppress the regrowth of any low numbers of engineered bacteria surviving chemical treatment. In theory, the engineered bacteria would die out, having been stressed by fumigation and high soil pH so that they would not be able to compete with the high number of organisms added to the site. Unfortunately, even the best state-of-the-art microbiological techniques can not show absolutely that a microorganism is completely eliminated from an environment. Therefore, we must rely on state-of-the-art scientific judgement. In any event, the engineered organisms produce very little toxin and would not be expected to cause adverse effects even if their population should increase to 10^6 cells per gram of soil.

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Question: Briefly describe what these emergency measures are.

Response: The contingency plans involve the following steps:

1. The crops and other plants within the one acre plot will be saturated with Amphyl detergent followed by saturation with sodium hypochlorite.

2. The plants will be killed with Paraquat.

3. The plants will be cut and placed to one side of the field in the buffer zone for fumigation with methyl bromide under a tarp.

4. The field will be fumigated with methyl bromide and covered with a tarp. After seven days, the soil will be limed to arrive at a pH greater than 8.5 and a layer (approximately 1 inch) of topsoil taken from another area of the test farm will be tilled into the test plot in order to reestablish normal bacterial flora.

5. The soil and dead plants will be monitored for the presence of the engineered organisms using enrichment techniques and the results reported to the EPA.

Question: Some scientists have stated that eradication under these conditions is not possible. Must we assume that once released, an engineered microbe cannot be recalled?

Response: Eradication of an organism in the environment depends on the properties of that organism. It is possible for an organism to be eliminated from the environment if it is less competitive than other species that are better adapted to grow under particular environmental conditions. Biological containment (the organism possesses characteristics that reduce or prevent dissemination, survival, multiplication, or certain biological activities in target or nontarget environments) could provide an effective means of controlling an engineered microorganism. This could involve

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inserting a temperature sensitive gene or deleting DNA repair capacity. To date, molecular biologists have not introduced these characteristics into potential products since they generally feel that it is so difficult to develop a microorganism that will survive well enough to express the desired characteristics that manipulations to introduce or increase biological containment will prevent the microorganisms from working at all. However, as indicated in the response to the first question, there are other means of controlling organisms. In summary, having an organism that will accomplish the desired task must be balanced against being able to eliminate it from the environment afterwards.

Question: Under these circumstances isn't the pre-release review our main real chance to assure safety?

Response: The pre-release review is very important to identify those cases which may present unreasonable adverse effects to the environment.

Question: Is this assurance of safety a burden that the current review process can meet?

Response: OPTS has been reviewing microbial pesticides sucessfully since its formation in 1970 and has evolved procedures for assessing risks of micro-organisms. The current review process builds on this experience, incorporating the aspects unique to bioengineering techniques, and includes extensive agency, inter-agency, and outside peer review of our risk assessments. Our reviews of genetically altered microbial pesticides have been favorably received by the outside reviewers. This experience demonstrates that it is possible to develop testing protocols and to perform risk assessments that will allow us to successfully regulate these microorganisms and to meet our statutory obligations of avoiding unreasonable adverse effects to the environment.

I hope you find our responses helpful. Should you need further information, please do not hesitate to contact me again.

Sincerely yours,

John A. Moore
Assistant Administrator
for Pesticides
and Toxic Substances

United States Department of Agriculture

Statement of Orville G. Bentley

Assistant Secretary for Science and Education

Before the Senate Committee on Environment and Public Works, May 16, 1986

Subcommittee on Toxic Substances and Environmental Oversight

Mr. Chairman and Members of the Committee, we wish to express the appreciation of the U.S. Department of Agriculture (USDA) for the opportunity to discuss with you how USDA is organized to review applications and notices related to intentional releases of genetically engineered organisms into the environment. We are also aware of the Committee's interest in USDA's granting of a veterinary biological product license for pseudorabies vaccine, modified live virus, issued to TechAmerica Group Inc. I have with me today Alan Tracy, Acting Assistant Secretary, Marketing and Inspection Services, who will respond to your questions regarding the product licensing procedures of USDA.

At this time, I would like to discuss briefly USDA's policy initiatives with regard to the development of biotechnology, including our role in the government-wide effort to provide a coordinated framework for regulating this new technology.

In response to the anticipated growth in the commercial application of genetic engineering technology, the Office of Science and Technology Policy (OSTP) in the Executive Office of the President published a "Proposal for a Coordinated Framework for Regulation of Biotechnology" on December 31, 1984 (49 FR 50856-50907) (hereafter December 84 Notice). The OSTP proposal included policy statements by the Food and Drug Administration (FDA), the Environmental

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Protection Agency (EPA), and the U.S. Department of Agriculture (USDA). As a part of its policy perspective, USDA believes that agriculture and forestry products developed by biotechnology will not differ fundamentally from conventionally produced products and that the existing regulatory framework is adequate to regulate biotechnology. USDA also has pledged to amend its regulations if developments indicated a need for additional oversight.

In the months since the OSTP proposal was published, USDA has taken steps that we hope will encourage promising developments in agricultural biotechnology, in both USDA-funded research projects and commercial product development, while protecting human health and the environment through the administration of existing statutes.

On April 19, Secretary Richard E. Lyng approved the establishment of an Office of Agricultural Biotechnology (OAB). It will be responsible for implementing and coordinating the Department's biotechnology policies and procedures, including the conduct of laboratory and field research, experimentation on biotechnological products prior to their commercialization, and all matters of oversight of biotechnology in agriculture. The new Office will report to the Assistant Secretary for Science and Education. We also intend to establish a structure of checks and balances to our activities. We intend to establish an interagency committee of Federal employees, the Committee on Biotechnology in Agriculture (CBA) which will address issues crossing agency lines, and an advisory committee to be known as the Agricultural Biotechnology and Recombinant DNA Advisory Committee (ABRAC), consisting of people with diverse expertise from the public and private sectors,

and a National Biological Impact Assessment Program (NBIAP). The OAB will provide staff support for these committees. The Assistant Secretary for Marketing and Inspection Services will continue to exercise the Department's existing regulatory responsiblities for licensing products developed through research.

In a July 19, 1985, Federal Register Notice (50 FR 29367-68) the Secretary of Agriculture delegated authority for coordinating the development and carrying out all matters and functions pertaining to the Department's regulation of biotechnology to the Assistant Secretary for Marketing and Inspection Services. These responsibilities were further delegated to the Administrator of the Animal and Plant Health Inspection Service (APHIS) In this same notice the Secretary of Agriculture delegated responsibility for coordinating the development and carrying out all matters pertaining to USDA-funded agricultural research in biotechnology to the Assistant Secretary for Science and Education.

An understanding of the way in which USDA has divided these responsibilities should prove useful to those seeking review and/or approval of biotechnology applications. The Assistant Secretary for Science and Education (S&E) oversees the research activities for the Agricultural Research Service (ARS), the Cooperative State Research Service (CSRS), the Extension Service (ES), and the Office of Grants and Program Systems (OGPS) USDA-funded research projects involving genetic engineering are currently overseen by the USDA Agricultural Recombinant DNA Research Committee (ARRC). The Assistant Secretary for Marketing and Inspection Services oversees the regulatory activities of APHIS, which includes Veterinary Services (VS) and Plant Protection and Quarantine (PPQ); the Agricultural Marketing Service (AMS), and the Food Safety and Inspection Service (FSIS). Applications for veterinary biologics licenses and permits and permit applications for plant pest

movement are regulated by APHIS. The Administrator of APHIS established a Biotechnology and Environmental Coordination Staff to assist him in fulfilling his regulatory responsibilities for biotechnology. This staff coordinates APHIS biotechnology regulatory initiatives as they regard product licensing and issuance of permits. The staff serves as a liaison between APHIS and other USDA agencies as well as other Federal agencies in regulatory matters. In the performance of these research and regulatory activities, there will be close coordination between the research and regulatory agencies in all cases involving genetically engineered organisms.

On September 23, 1985, APHIS published guidelines in the Federal Register (50 FR 38561-63) for the control and protection of documents containing confidential business information (CBI) concerning biotechnology. The protection of CBI is understandably a concern of industry, and the protection of trade secrets was urged by numerous commenters representing biotechnology companies. The USDA guidelines are based upon the confidential business information exception contained in the Freedom of Information Act (FOIA).

USDA is preparing a Departmental policy statement on research and regulation of biotechnology for publication in the Federal Register. Similar statements are being prepared by NSF, FDA, EPA, NIH, and OSHA as a part of a coordinated policy statement that refines and expands upon the December 1984 Notice. The USDA policy statement will describe proposed guidelines for oversight and safe conduct of Federally-funded agricultural biotechnology research.

The USDA policy statement includes a description of proposed new regulations under the authority of the Federal Plant Pest Act (FPPA) and the Plant Quarantine Act (PQA) for genetically engineered organisms which are plant pests.

USDA, pursuant to the FPPA and the PQA regulates the movement into and through the United States of plants, plant products plant pests and any product or article which may contain a plant pest at the time of movement. These articles are regulated in order to prevent the introduction, spread or establishment of new plant pests in the United States. The regulation proposed by APHIS for regulation of genetically engineered organisms would require a permit prior to the release into the environment of a genetically engineered microorganism which presents a risk of the introduction, spread or establishment of a plant pest. Permit requests would be filed with USDA, APHIS, Plant Protection and Quarantine. Also explained in the USDA policy statement are the procedures APHIS follows in licensing veterinary biologics regulated under the Virus-Serum-Toxin Act of 1913, 21 U.S.C. 151-158, (VSTA) which may be derived by recombinant DNA techniques or developed from hybridomas.

Under the VSTA, the USDA (APHIS) (VS) has exercised regulatory authority over all veterinary biologics imported into the U.S. or shipped or delivered for shipment interstate. Recent amendments contained in the Food Security Act of 1985 have extended this authority to products which are shipped intrastate or exported, and have given USDA additional enforcement mechanisms such as the power to detain and seize products. Under the VSTA, veterinary biologics may not be sold, shipped or delivered for shipment if they are worthless, contaminated, dangerous, or harmful. The Secretary now has the authority to regulate the distribution of all unlicensed biologics, subject to the statutory exemptions, whether shipped interstate or intrastate. Prior to the recent VST amendments, USDA authorization was required for the interstate distribution or experimental unlicensed biologics. Regulations are now being prepared by APHIS which will extend these requirements to intrastate movements as well. For the purposes of licensing, biologics derived by recombinant DNA-techniques or developed from hybridomas may be classified into three broad categories based on the biological characteristics of the new products and the safety concerns they present.

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The first category includes inactivated recombinant DNA-derived vaccines, bacterins, bacterin-toxoids, virus subunits, or bacterial subunits. The second category includes those products containing live microorganisms that have been modified by the addition or deletion of one or more genes. The third category includes products using live vectors to carry recombinant-derived foreign genes that code for immunizing antigens and/or other immune stimulants.

Prior to release of organisms in either of the first two categories, precautions are taken to assure that those projects pose no risk to the environment. The third category, using live vectors, will not be considered for licensing until questions concerning characteristics of safety and transmission can be fully answered.

TechAmerica Groups Inc. was issued a license for OMNIVAC, a genetically engineered thymidine kinase negative (TK-) pseudorabies vaccine which is a second category product because it contains live microorganisms that have been modified by the deletion of a gene. This license was issued pursuant to the regulations found in 9 CFR 101 and included the additional safeguards I just spoke of. A two- week voluntary suspension was agreed to by the Department and TechAmerica to permit USDA to provide full documentation describing the analytical steps that had been taken to ensure that the product was environmentally safe. Environmental questions about stability, survival, persistence, and dissemination were identified and resolved by APHIS officials prior to licensing of the vaccine. The Environmental Assessment, which presented a finding of no significant impact, fully documents the Department's review and analysis of environmental impacts and supports the Department's licensing of this product.

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Let us now look at the role of Science and Education and the ARRC in reviewing requests for field testing genetically-engineered organisms. USDA is in the process of publishing USDA Guidelines for Biotechnology Research that will closely parallel the NIH Guidelines and will be issued under the authority of the Food Security Act of 1985 (Public Law 99-198). The amendment gave the Secretary of Agriculture responsibility for establishing "appropriate controls with respect to the development and use of the application of biotechnology to agriculture."

All Federally-funded agriculture biotechnology research or agriculture research conducted at an institution receiving USDA funds would be subject to the USDA guidelines for Biotechnology Research unless the specific research project is supported by and subject to the guidelines or regulations of another Federal agency. These guidelines would encompass all phases of agricultural biotechnology research such as: contained laboratory experiments; specialized isolation research. (For example a greenhouse or a biotron); and research involving release into the environment. To encourage voluntary compliance from industry, USDA proposes to adopt the NIH policy of providing the researchers not required to comply with these guidelines the opportunity to have their new biotechnology research proposals voluntarily reviewed by USDA.

We have developed a system of oversight of biotechnology research in agriculture based largely on our participation in the NIH-RAC process for the past 10 years through the NIH-RAC. I will propose that the Secretary replace the current Agricultural Recombinant DNA Research Committee (ARRC), with ABRAC, a system also closely patterned after the existing NIH-RAC.

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We are in the process of establishing a National Biological Impact Assessment Program to provide support in the evaluation and monitoring of the potential impacts of biotechnological processes and products on safety and the environment. From the earliest concerns about recombinant-DNA research in the mid 1970s, USDA has been actively involved and supported the National Institutes of Health (NIH) officials during the formative stages of their recombinant-DNA advisory committee generally known as the NIH/RAC. Agricultural scientists have been in attendance and members of the NIH/RAC since its first meeting. Agricultural scientists, including a member of the USDA Agricultural Recombinant DNA-Research Committee (ARRC), are members of the NIH/RAC Plant Working Group.

A major portion of the Agricultural Recombinant DNA Research Committee's (ARRC) time since the fall of 1983 has been devoted to helping to develop the USDA's statement of policy for Research and Regulation of Biotechnology Processes and Products. This statement of policy has been in response to the Office of Science and Technology Policy's effort to provide a coordinated framework for regulation of biotechnology.

ARRC's role in the review of applications to field test genetically-engineered products is to provide scientific advice. In the University of California proposal to field test a genetically engineered or "ice-minus" bacterium, the NIH/RAC recommended approval of the field test, but only after asking the ARRC to also review this request and make a recommendation to it. The ARRC conducted their own review and recommended to the NIH/RAC that the proposed field test be approved. This is the procedure that has been followed by the NIH/RAC and the ARRC in dealing with any agriculturally-related requests that have come to the NIH/RAC.

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In addition, current EPA policy states that they must be notified prior to all small scale field tests involving certain microbial pesticides, in order to determine whether experimental use permits are required. This is a change from their earlier policy that prior notification and experimental use permits were not required for any 10 acre or less field tests of microbial pesticides. The EPA policy also emphasizes the inclusion of microorganisms genetically altered or manipulated by humans. With this EPA announced policy and the OSTP's efforts over the past couple of years to develop a better coordinated approach in the regulation of biotechnology, the ARRC has been invited to send representatives to sit in on several of EPA's scientific advisory panel sessions considering prior notification of desired small scale field testing of genetically engineered microbial pesticides.

The ARRC has reviewed only one proposal for field testing of a genetically-engineered product since publication of the Department's proposed biotechnology regulatory policy in the Federal Register notice of December 31, 1984 and that was a product produced by Calgene Inc. as to which review is not final.

Mr. Chairman, we believe the establishment of the Office of Agricultural Biotechnology, and the pending publication of the Federal biotechnology policy statement will alleviate any confusion which has existed as to the separate issues of research and product licensing.

My colleague and I will now be pleased to answer questions.

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DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

July 25, 1986

Dr. Ronald B. Outen
Committee on Environment and
Public Works
United States Senate
Washington, D.C. 20510

Dear Dr. Outen:

Pursuant to your request dated June 25, 1986, we are submitting the following information in answer to questions by Senators Burdick and Baucus regarding the government approval of the release of genetically-engineered organisms.

We apologize for the delay in responding to your request.

Sincerely,

Orville G. Bentley

ORVILLE G. BENTLEY
Assistant Secretary
Science and Education

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ANSWERS TO QUESTIONS FOR DR. ORVILLE G. BENTLEY FROM SENATOR BAUCUS

1Q. Would you agree that releases of genetically engineered micro-organisms into the environment are unlikely to pose health risks to the public?

1A. Our mission is to assure that release of genetically engineered microorganisms into the environment will not pose health risks or any other risks to the public. This will be achieved through the scientific process used in determining whether or not these organisms should be released. The USDA National Biological Impact Assessment Program will monitor any changes which might occur over long periods of time to determine any potential health risks.

2Q. Let us suppose that an altered organism released into the environment did become in some capacity dangerous. Would you agree that the effects could potentially be disasterous?

2A. We do not believe that an accidental release of an altered organism could be disastrous anymore so than some of the natural occurring organisms in nature. For example, many virilant organism strains that occur naturally are controlled by the system in which they are released. If natural forces fail to control an organism, it builds for itself a new ecological niche. Man responds accordingly to contain this event in nature. We believe this potential is far less for altered organisms than natural organisms because of the types of testing and the continual incremental assessment of the ability of a given microorganism to develop into a problem.

The biological impact assessment program which will allow us an early detection process that, in the event that such a problem might occur, it would enable us to react directly and quickly to control any potential harm.

3Q. If one of these altered organisms that was dangerous was released, would it not be different than the release of a dangerous chemical, in that it could reproduce, spread and not have the possibility of being recalled.

3A. Yes, however, there is a substantial recall process. We engage in recall processes in naturally occurring phenomena continuously which is the nature of agriculture itself. The spreads of extremely virulent strains of various rusts, bacteria, and viruses are a continual challenge to our arsenal of methods to contain and to recall potential effects from these agents. We see daily every evidence that this indeed is being successfully accomplished.

4Q. Couldn't some of these gene altered organisms potentially last for generations, or indefinitely?

4A. It is not an unreasonable question in that the scientific community is faced with that question continually in designing genetic consequences for microorganisms in balance with higher organisms. Certainly in the case of desired genes, stability of a given genome will be sought to gain those benefits. Wherein there is a harmful or a potentially harmful genome, a

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specific bio containment that ends the life of that gene must be built into the organism before there is release into the environment. Failure to do so would put us into the realm of the points raised in Question 3 and recall processes to avoid the indefinite appearance of that gene in the environment would have to be utilized.

5Q. Isn't there an analogy than one can draw, to some degree, between the biotechnology industry and the nuclear power industry. In the sense that both pose low probability/high occurrence risks? Meaning, if an altered organism that was released into the environment did turn out to be pathogenic, that it would spread far beyond the area of original release.

5A. The nuclear power industry poses low probability and potential high risks. By comparison, we consider the biotechnology industry to be low probability and low risk by many orders of magnitude in comparison. Not only would the rate and amount of spread be less, but also the time element required to lessen any damage would be infinitely smaller. Further, the spread of microorganisms from their original area of release, would be especially small. By comparision the potential for spread, with detection systems and recall process available, would result in an extremely limited involvement.

6Q. USDA has rigorously pursued a program to ban hundreds of non-native organisms from entering the United States. These non-native organisms could potentially cause hundreds of millions of dollars of damage, and you wouldn't be able to get rid of them. What would the potential $$ loss be if one of these non-native organisms did enter the United States?

6A. We do not have a figure to give you of what the total dollar loss would be if a non-native organism might enter the United States. Millions of non-indigenous organisms reach our shores constantly and never establish an ecological niche. Many non-native organisms that have reached our shore were welcomed. For example, none of our major crops were indigenous to this Nation. Also, there is no economic crop produced in the United States that does not contain genes that were not indigenous to this Nation before their introduction. The question of containing and keeping a balance of biologics, both in our nation as well in other Nations where they are concerned about non-indigenous materials, seems to us to not be changed as a result of biotechnology. This line of thought also applies to question 7.

7Q. Would the effects of a pathogenic bio-engineered microorganism be similar to the effects of one of these non-native organisms?

7A. The answer of number 6 substantially answers this question.

8Q. Have you ever been able to limit, contain, or clean up the damage caused by a non-native organism, like dutch elm disease, or chestnut blight?

8A. Yes, many times nature has accomplished this without our help. There are questions as to whether or not non-indigenous or non-native organisms were really non-native at all. The point being, large masses of biological materials, such as plants, leave imprints on microorganisms in massive culture, and nature's variance can produce strains which are

identical to strains off our shores without their being introduced. There is much interest today in the fact that the fungus that causes dutch elm disease is a genus that may have been widely spread and well known in this Nation long before dutch elm disease was noted. The same is true with chestnut blight. The causitive agent is widely occurring on oaks in the U.S., but it has not destroyed the oaks. In both instances, utilizing biotechnology techniques, there is a good probability that a resistance against these diseases may be developed, and we may be able to restore the American elm and the native chestnut to their former grandeur.

9Q. Are you aware that biotech firms and research facilities have been unable to secure or afford liability or contamination of the environment insurance, and have instead chosen to go "bare", assuming liability as a business risk against their capital?

9A. We have been told of such matters, but it is not part of our documented literature. The magnitude or the degree that this situation exists has not been determined.

10Q. Has the agency held any meetings to discuss with the biotechnology industry the issue of insurance coverage or liability? If so, what have the nature of these meetings been? Has the agency looked into the issue of liability issurance? Do you discuss liability with the applicants?

10A. To our knowledge, this area has not been pursued within the Department at this time.

11Q. Why is it that the insurance industry believes that it is too risky to cover biotech firms and research facilities for environmental releases, yet federal agencies continue to approve environmental releases?

11A. With the publication of Federal Register, June 26, 1986 (51/23302-23393) "Coordinated Framework for Regulation of Biotechnology" there will be a framework available from the Department of Agriculture that will lay this process out and should give the insurance industry an opportunity to develop proper actuarial background to offer insurance in this area.

12Q. Shouldn't the American public know who is responsible if an altered microorganism does cause a problem?

12A. Our National Biological Impact Assessment Program will provide thorough and immediate information to the American public on any microorganism produced through biotechnology or any other organism causing a problem. This will be a national system which covers the entire nation; it will be computer driven and will be able to provide instant data for anyone that wants to check a program at any time. We also are planning an alert system if needed to provide the public news access.

13Q. Is it conceivable that a release of an altered microorganism could become destructive, or a pest?

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13A. We have already covered 13 earlier. Please refer to the answer of question 2.

14Q. Who would be liable if a problem were to arise from an environmental release.

14A. That would depend upon the circumstances underlying the particular problem.

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DR. ORVILLE G. BENTLEY RESPONSES TO QUESTIONS OF SENATOR QUENTIN N. BURDICK

1Q. Under existing Federal regulation, can a private company develop a recombinant DNA farm product, which is a live organism or virus, and release it into the environment for field testing without informing USDA? If yes, do you think this is acceptable?

1A. Under existing Federal regulations a private company would fall under either USDA or EPA regulations as they relate generally to microorganisms and specifically to plant pests, pathogens or pesticides. Regulation responsibilities relating to microorganisms in the "Coordinated Framework for Biotechnology" have been carefully assigned between EPA and USDA in relation to the legal responsibility and expertise of each agency. In addition, if a biological product is involved it would require a license from USDA and all background and tests would fall under APHIS purview.

2Q. USDA has been the lead agency in working with a private company to develop the recently introduced swine vaccine. However, the field testing was done without consultation with the Federal government. Does the USDA have any problems with ensuring that private companies comply with the voluntary guidelines as written by the National Institutes of Health?

2A. In relation to the recently introduced recombinant DNA derived swine vaccine, the institutions involved during the research phase were under the NIH Guidelines for Biotechnology Research. Therefore, it appears that the Guidelines should have been followed. NIH currently has this case under review by a scientific panel to determine to what extent the institutions might have erred.

The USDA strongly recommends that all applicants establish Institutional Biosafety Committees which follow applicable provisions of the NIH Guidelines for Research Involving Recombinant DNA Molecules (USDA Policy Statement, Federal Register, June 26, 1986 (51 FR 23336).

2aQ. Texas A&M, Baylor Medical College, and the National Institutes of Health have all stated that the swine vaccine is a recombinant organism. Yet its release was never reviewed by the Institutional Biosafety Committees as required by the NIH-RAC guidelines. Does this constitute non-compliance with USDA procedures?

2aA. This does not constitute non-compliance with USDA procedures.

3Q. How many formally trained ecologists are employed by USDA and were they involved in assessing the safety of the swine vaccine and in writing the environmental assessment?

3A. In the Cooperative State Research Service and State Agricultural Experiment Station System there are many ecologists. There are 12 formally trained ecologists in the Agricultural Research Service (ARS). In the entire USDA there are additional ecologists the exact number of which is not available.

The tabulation of these is in the beginning stage for the National Biological Impact Assessment Program (NBIAP) being developed as a part of the Coordinated Framework for Regulation of Biotechnology by the USDA. The scientists with expertise in animal disease and immunization who were the most appropriate officials assessed the safety of the swine vaccine.

4Q. According to GAO, there is an internal conflict within USDA between the Agricultural Research Service and the Animal Plant Health Inspection Service. What has been done to resolve this management problem?

4A. The specific USDA Offices involved were Science and Education and Marketing and Inspection Services. Time was required to sort out the myriad areas involved, being very careful to assure that each agency fulfilled its legal mandates as well as utilizing the competencies available. Through many hours of meetings between all concerned, the responsibilities have been carefully determined for each agency within the USDA. The goals have been to assure the public that there is comprehensive review, while at the same time that duplication is reduced to a minimum. Of course as the system continues to operate, refinements are expected

5Q. Are applicants free to shop between these two agencies on deciding where to file their applications to perform a release? If no, why were two virtually identical applications for the release of engineered tobacco plants handled by separate USDA agencies? What steps will be taken to assign application and to coordinate interagency activities?

5A. The Office of Agriculture Biotechnology was formally created July 14, 1986 by the Secretary of Agriculture. Notice of all applications for recombinant DNA approval will be sent to and recorded in this office. The OAB will insure that each applicant will receive the proper review.

6Q. Does USDA plan on approving any organisms for release which have not been fully reviewed and approved by the USDA Agricultural Recombinant DNA Research Committee, or by its future replacement, the Agricultural Biotechnology Recombinant DNA Advisory Committee.

6A. In the Coordinated Framework for Regulation of Biotechnology all microorganisms come under the purview of USDA or EPA. The definitions of the organisms that need to be regulated are in these documents. It has been USDA policy that any research involving organisms supported by Federal funds will fall under the NIH Guidelines for Biotechnology Research, but will fall under the proposed USDA Guidelines for Biotechnology Research when approved. The ARRC or NIH RAC can handle these matters as they relate to agriculture.

7Q. GAO reports that USDA funded at least 87 experiments which could eventually lead to a release of genetically engineered organism, yet only a small minority of these experiments include any kind of risk assessment. Why doesn't USDA require a risk assessment on all experiments in which an eventual release is likely?

7A. All of the 87 experiments have had a very thorough incremental risk assessment during various stages in their development during the research process. This is consistent with the RAC process, i.e. risk assessment is a step by step process each step finished before the next step in research is taken.

8Q. I understand that USDA will promulgate guidelines for biotechnology. Please provide for the record, the definitions under consideration by the agency for: genetically engineered organism, recombinant DNA organism, containment, and release.

8A. The definitions being considered in the Advance Notice of Proposed USDA Guidelines for Biotechnology are outlined in some detail. Federal Register June 26, 1986 (51/23367-23393). It should be noted that some of the definitions are still in a formative stage undergoing scientific and public scrutiny and comment. The final decision on definitions will be at the time the guidelines are promulgated. Specifically descriptive material and definitions can be found as indicated below:

1.&2. genetically engineered organism and recombinant DNA organism - (FR-51, 22369-23370).

3. containment - Containment in general relates to the classes of organisms and their inherent toxicity involved in specfic research activities. This is very complex and defined in both physical and biological terms. (FR-51, Subpart .3 Containment, 23377-23389).

4. Release - definitions of release are under study by scientists and will be resolved at the time of publication of the proposed guidelines for research.

THE AGRICULTURAL STATUTES AS A BASIS FOR REGULATING THE RELEASE OF ENGINEERED ORGANISMS

WRITTEN STATEMENT

submitted by Margaret G. Mellon
Environmental Law Institute

In the 1984 OSTP proposal for the coordinated Framework for Regulation of Biotechnology, the United States Department of Agriculture ("USDA") announced its intention to regulate agricultural applications of biotechnology under the potpourri of statutes that it currently administers. Below are brief analyses of the five major statutes that USDA has at its disposal to accomplish that regulation.

Virus-Serum Toxin Act

The Virus-Serum Toxin Act is a licensing statute which provides strict premarket testing and review of organisms which are themselves classified as veterinary biologics or which are involved in the production of veterinary biologics. 21 U.S.C. §§151-158. The VSTA provides the USDA with authority to regulate the import, export, and the intrastate and interstate transport of veterinary biological products. Such products are defined as "all viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, and killed microorganisms intended for use in the diagnostics, treatment, or prevention of diseases of animals." 9 C.F.R. §101.2(w). (emphasis added).

Veterinary biologics must be prepared in USDA-licensed establishments and each product must be individually licensed for production. 9 C.F.R. §102.1. Product license applications require the submission of test reports and data establishing purity, safety, potency, and efficiency of the product. 9 C.F.R. §102.3(ii). "Safety" refers to the adverse effects on the recipient of the drug or treatment, not broader environmental

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effects. Id. The importation of veterinary biological products also requires a USDA permit. 9 C.F.R. §104.1.

The VSTA does not cover academic research with engineered organisms except to forbid the production of experimental biological products at a licensed facility. 9 C.F.R. §103.1.

In terms of its application to genetically engineered organisms, the VSTA is useful but limited. The statute covers only organisms intended for a particular commercial use — veterinary treatments. It does not cover research activities, even where they might involve release. The VSTA is, however, the only one of the agricultural statutes under which prelease reviews of biological organisms are routinely conducted. Adequate regulation of bioengineered organisms under the statute would require revision of the currently applicable test requirements to specifically address the ecological effects of release.

Act of February 2, 1903

USDA has additional authority to protect animals under the Act of February 2, 1903. 21 U.S.C. §111. The Act provides USDA the authority to make such regulations and take such measures as are necessary to prevent the introduction of contagious, infectious, or communicable disease of animals and/or live poultry from a foreign country into the United States or District of Columbia, or from one state to another. The Act applies to both disease organisms and their vectors.

In the context of genetic engineering, the statute would be most useful to prevent the introduction or halt the spread of genetically engineered organisms that turned out to be infectious agents of animal disease. It does not provide pre-release review or testing of organisms to determine if they possess this or any other unwanted property.

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The Plant Pest and Plant Quarantine Act

The Plant Pest Act regulates the importation and interstate movement of plant pests, and any products or articles which may contain a plant pest at the time of movement, unless authorized under a general or specific permit from USDA. 7 U.S.C. §§150aa-150jj. The purpose of the statute is to protect against the introduction or dissemination of plant pests.

The statute applies to a wide variety of organisms and parts of organisms which present a risk of introducing, spreading or establishing plant pests. These include:

> "insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses or any organisms similar to or allied with any of the foregoing or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plant or parts thereof, of any processed, manufactured, or other products of plants." 7 U.S.C. §150aa(c). (emphasis added)

Not included are non-parasitic plants, vertebrates including fish and mammals, and organisms beneficial to plants.

The Plant Pest Act supplements and extends the older Plant Quarantine Act, which prohibits the importation of nursery stock into the United States without a permit obtained from U.S.D.A. 7 U.S.C. §§154-164. Nursery stock is defined to include trees, shrubs, and vines, but excludes herbaceous plants, a category which includes most crop plants. 7 C.F.R. §152.

As a vehicle for regulating genetic engineering, the Plant Pest Act has the advantage of covering a broad variety of the organisms, including viruses and bacteria, that are likely to be among the genetically-engineered products. Moreover, its coverage is not restricted by the purpose or activity within which the organism is used. The statute authorizes a permit system that might possibly be expanded into a pre-release review system. USDA's jurisdiction under the statute, however, is limited to organisms

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which "directly and indirectly injure crops or other useful plants," a major drawback for the establishment of a pre-release review program. Narrow interpretations of the "can injure" language could exclude from the statute's jurisdiction those plants whose full range of properties are not yet known, a category which would likely include newly developed engineered organisms. Without jurisdiction over such organisms, the statute cannot be used to compel the performance of tests as a condition for a permit. Organisms beneficial to plants are also apparently excluded from the statute's coverage.

Finally, the authority under the Plant Pest Act is limited because it does not extend to intrastate movement of organisms. Thus USDA might have difficulty reaching organisms so long as they were produced and kept within the boundaries of a given state. This limitation might restrict the ability of the USDA to regulate some field releases by academic scientists.

Noxious Weed Act

Complementary to its authority to regulate organisms that are pests upon plants, USDA also has authority under the Noxious Weed Act to regulate plants that themselves are kinds of pests. 7 U.S.C. §§2801 et seq. The Act prohibits the movement of noxious weeds into or through the U.S. or intrastate, without a permit.

> Under the Act, noxious weeds are defined to include living stages of any plant "which is of foreign origin, is new or not widely prevalent in the United States, and can directly or indirectly injure crops and other useful plants, livestock, or poultry or other interests of agriculture, including irrigation, or navigation, or the fish or wildlife resources of the U.S. or the public health." (emphasis added)

Under the listing provisions of the Act, plants can be identified as "noxious weeds" only if their dissemination may reasonably be expected to have to a serious degree any effect specified above. 7 U.S.C. §2809.

This statute has been suggested as the basis for a pre-release review program to regulate all genetically-engineered plants. Such a program would be a dramatic expansion of the post-release permit program currently administered. Like the Plant Pest Act, extension with the area of pre-release review would encounter jurisdictional problems. In language similar to that of the Plant Pest Act's, the Noxious Weed Act covers only those plants that "can directly or indirectly injure" identified interests. As in the case of the Plant Pest Act, that language appears to foreclose the regulation of plants whose environmental effects have not yet manifested themselves.

Summary of Agriculture Statutes

The agriculture statutes are clearly inadequate as the legal basis for a comprehensive, pre-release review program regulating the full range of the agricultural applications of biotechnology. First, taken together, the statutes fail to cover the full range of organisms that might be constructed using the new techniques of biotechnology. Each of the statutes' jurisdiction is restricted either to certain kinds of organisms (plants) or to organisms used for certain purposes (veterinary biologics) or possessing certain properties (e.g., being plant pests). The result is a crazy quilt of coverage unrelated to the potential for causing ecological effects. The statutes do not apparently cover, for example, either organisms beneficial to plants or crop plants themselves, although both are generally as likely to disturb the environment as are organisms fitting the definitions of plant pests or noxious weeds.

Second, except for the VSTA, the statutes do not provide explicit authority for pre-release review of organisms. The agricultural statutes are intended to remedy rather than to prevent problems. They empower USDA to prohibit the movement or to seize

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and destroy organisms that have previously manifested themselves as harmful to agricultural interests in some way. As they are now implemented, the statutes do not require testing of organisms to determine whether they are harmful, nor the notification of USDA of the possession of a plant that might pose such risks.

It is possible that USDA might attempt to elaborate a pre-release review system as a requirement for transport permits under the Noxious Weed or Plant Pest Acts. If so, the establishment of a pre-release review program would encounter at least one jurisdictional hurdle. Both the Noxious Weed Act and the Plant Pest Act appear to cover only organisms "known to directly or indirectly injure" either plants or other identified interests. This jurisdictional language would appear to preclude application of the statute to require testing of organisms whose ecological effects were unknown, unless a case could be made that all genetically-engineered organisms can directly or indirectly injure plants or other identified interests. Currently available scientific information would not appear to support such a sweeping assertion.

Third, the purpose of these statutes is the protection of agriculture rather than the environment. It is noteworthy that currently USDA does not concern itself with the broad ecological impacts of the crops, flowers, or stock animals produced by genetic engineering techniques, except insofar as the organisms can be considered agricultural pests, noxious weeds, or agents of contagious disease. If these statutes are used to establish a program that primarily protects the environment, eventually cases will arise in which agricultural interests conflict with environmental interests. It is not clear in such situations the degree to which USDA, acting under these statutes, would be required, or even able, to protect the environment.

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ANSWERS TO QUESTIONS PRESENTED BY SENATOR QUENTIN N. BURDICK AS A FOLLOW-UP TO THE BIOTECHNOLOGY HEARING OF MAY 16, 1986 BEFORE THE SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS.

SUBMITTED BY

Margaret G. Mellon, Ph.D., J.D.
Environmental Law Institute
July 24, 1986

1. Are there situations in which a genetically-engineered organism or virus could be released without previous review by a government regulatory body, without violating any law?

   Yes. Even under the Coordinated Framework for the Regulation of Biotechnology issued July, 1986 there are many circumstances under which a genetically-engineered organism could be released into the environment without government review and without any violation of any law. Please consider the following.

   1. Organisms regulated under TSCA. TSCA is not a permit statute. It does not require that EPA review all proposed releases of engineered organisms. Instead, it requires that companies provide EPA notice and opportunity to review products. Under TSCA's notice system any organism that EPA does not get around to reviewing within the prescribed 90-day notice period legally goes onto the market without any review.

      All commercially-produced organisms are included under TSCA's jurisdiction.

   2. Organisms regulated under the agricultural statutes. Under USDA's policy, any organism generated in the process of non-federally-funded research that is not a plant pest or a veterinary biologic may be released into the environment without federal review. Voluntary review by the Agricultural Biotechnology Recombinant DNA Advisory Committee (ABRAC) is offered and encouraged, but not required.

      Pre-release reviews of some organisms will be required under the Plant Pest Act, but these reviews will be perfunctory. According to USDA's statement of its policy, the Plant Pest Act review will be based on existing data that will cost companies about $5,000 to assemble. The objective of the review will be to determine whether organisms are plant pests. Such a review does not address the central concerns about the environmental safety of engineered organisms and will not be adequate to identify and control organisms that present environmental risks.

      Note that almost all engineered plants and animals are within the jurisdiction of USDA. The exceptions are the few organisms regulated as foods or food additives under the Food, Drug and Cosmetic Act.

2. What extensions of current law would be necessary to close the loopholes in the existing regulatory structure?

   Obviously, many different legislative approaches would be possible to provide a meaningful review of the ecological impact of genetically-engineered organisms. In my opinion, new legislation is most needed to establish an integrated program to review and control the agricultural uses of genetically engineered organisms. The program could be set up within either USDA or EPA. My preference is for EPA, but with a sufficiently clear direction from Congress, USDA might be able to do the job. Ideally, the elements of the new program would include:

   1) A mandate to protect the environment.

   2) A flexible system for the pre-release review of commercial and non-commercial releases of engineered organisms.

   3) A research program aimed at defining the nature of environmental risk from genetically-engineered organisms. The research program would develop protocols for risk assessment and collect and evaluate the data generated in the testing and monitoring of products.

3. Under existing federal regulation, can a private company, which doesn't receive federal funds, develop a recombinant DNA farm product, which is a live organism or virus, and release it into the environment for field testing without informing USDA?

   Under the policy announced in the July 1986 Coordinated Framework for the Regulation of Biotechnology, unless the organism is intended for use as a veterinary biologic or is a plant pest, the answer is unequivocally, yes.

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July 3, 1986

Dr. Ronald B. Outen
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Dear Dr. Outen:

Enclosed are the answers to questions posed by Senator Burdick that resulted from the recent subcommittee hearing on biotechnology.

1. It would seem that the federal government lacks a consistent approach in regulating the biotechnology industry. Has this discouraged research because of the uncertainty of eventual commercial production?

IBA believes that the recent lengthy deliberations over regulatory policy have not affected commercial research ventures. Most of the biotechnology projects in development prior to the recently issued guidelines (51 FR 23302) were subject to regulatory certainty because they were either animal or human drugs subject to FDA regulation, or microbial pesticides subject to EPA regulation. Other projects in the agricultural or microbial waste degradation area are still in very early stages of research and development and extensive testing is needed to decide whether or not such organisms will be viable commercial products.

2. Do you have any specific recommendations to improve the federal regulatory structure?

Jurisdictional boundaries and procedural guidelines need to be clearly delineated. We hope that the recently issued coordinated framework will accomplish this and preclude the need for legislative correction of the statutes. IBA is in the process of reviewing the policy statement and will forward comments on it to the subcommittee.

3. How does industry in general view the federal governments reaction to the USDA swine vaccine case and the $20,000 EPA fine against Advanced Genetic Sciences? Do you believe that both of these products are properly classified as recombinant organisms, and as such subject to the NIH voluntary guidelines?

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Our reading of the NIH Guidelines indicates that these organisms are not recombinant organisms. Section I-B of the Guidelines defines recombinant DNA molecules as those "...constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell." It is clear that gene deletion products do not fall into this category. In our comments to the December 31, 1984 policy proposal for a coordinated framework, IBA took the position that these directed mutagenesis protocols duplicate processes that could occur in nature and should not be signaled out for special regulation. On the basis of the public record it appears that USDA conducted a review that was appropriate for this new swine flu vaccine. IBA has viewed the question of whether Advanced Genetic Sciences violated FIFRA statutory requirements as a question to be resolved between the company and the agency. We would point out the EPA recently settled the case by reducing the fine to $13,000, dropped a charge that the company had falsified experimental data and faulted the company only for inadequate reporting.

4. In your testimony you stated that both the swine vaccine and the ice-minus bacteria were not different from existing organisms. Is the release of these organisms or organisms like these, necessarily risk free? If no why not?

It is difficult to make a clear statement that anything will be 100% risk free, but in these two cases the scientific evidence points to minimal risk if they are used in the environment.

5. Should the ice-minus bacteria and the swine vaccine be subject to regulatory review for safety prior to their release into the environment?

IBA is not clear whether this question refers to introduction of the product at the field research stage or the commercialization stage. It is clear that each product has to meet certain requirements prior to commercial licensing and these requirements are designed to assure the safety of the product. IBA has taken the position that the review of biotechnology products is best accomplished on a case-by-case basis. Certain products will be reviewed at the field testing stage by the appropriate federal agency if there are scientific uncertainties about the environmental use of that product. IBA believes that this is a prudent approach.

IBA hopes that these responses will clarify some of the statements that were made in our prepared testimony.

Sincerely,

Alan Goldhammer

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